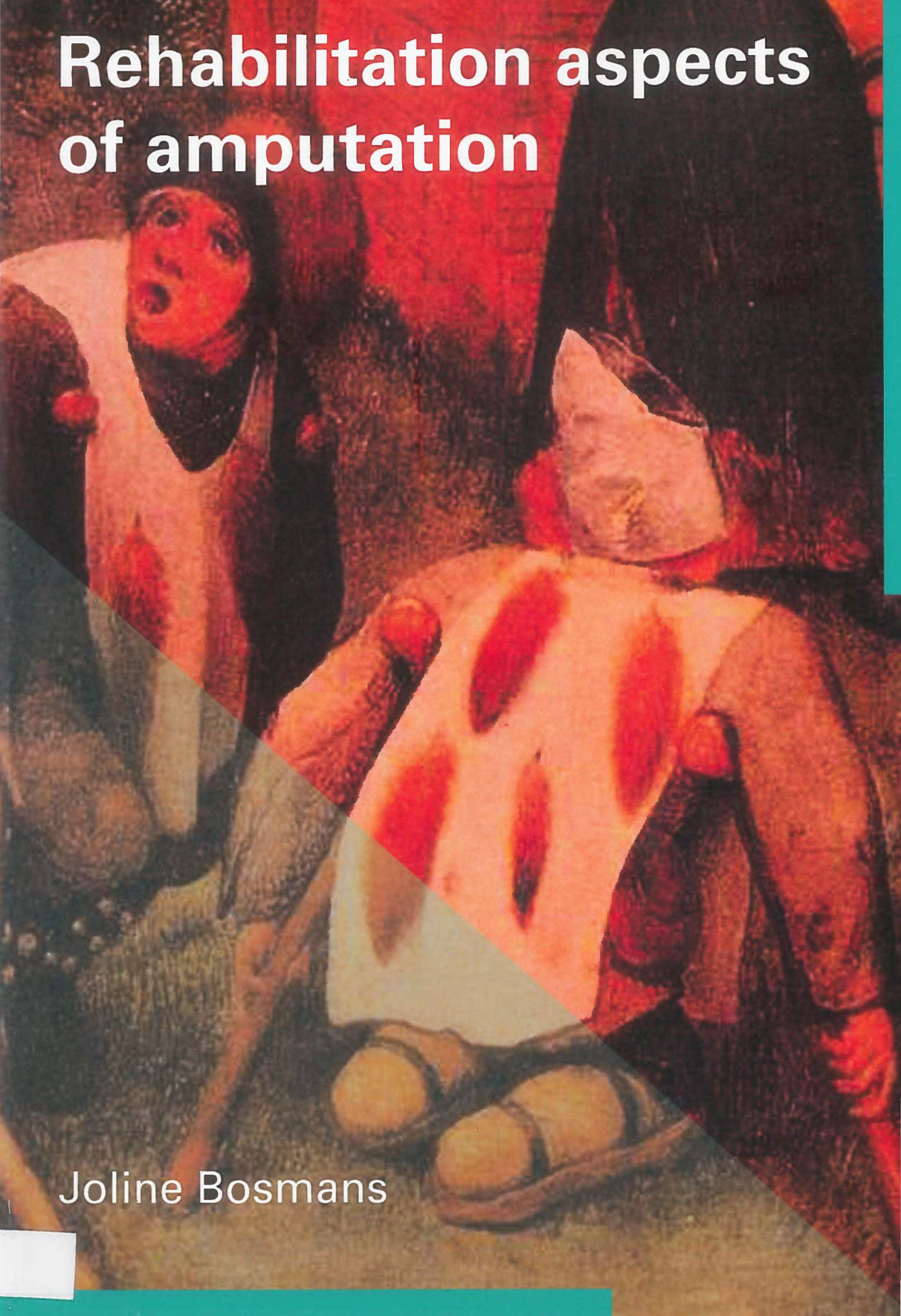
Rehabilitation aspects of amputation

Bosmans, Johanna Carolina

Rehabilitation aspects of amputation



Joline Bosmans

Stellingen

behorende bij het proefschrift

Rehabilitation aspects of amputation

1. De invloed van fantoompijn op kwaliteit van leven is beperkt (dit proefschrift).
2. De kans op fantoompijn is groter bij vrouwen, bij patiënten met een beenamputatie en in de eerste maanden na de amputatie (dit proefschrift).
3. De algemene klanttevredenheid met een orthopedische instrumentmakerij hangt af van de leeftijd van de klant en van de soort voorziening (dit proefschrift).
4. Het niet beschrijven van afkappunten voor fantoompijn schept verwarring in fantoompijnonderzoek (dit proefschrift).
5. Bij de beslissing een transfemorale amputatie te verrichten moet een knie-exarticulatie overwogen worden (dit proefschrift).
6. De kans om na een beenamputatie 500 m of meer te kunnen lopen neemt af bij een hogere leeftijd, een meer proximale amputatie en bij meer amputatiegerelateerde klachten (dit proefschrift).
7. Fantoompijn lijkt een grotere impact te hebben op onderzoekers dan op patiënten.
8. "It is not the strongest of the species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change." (www.darwinproject.ac.uk)
9. Eeuwig duurt het langst.
10. Er is niks tegen vooroordelen, als ze maar geregeld bevestigd worden (Sylvia Witteman).
11. Een mens is nooit te oud om te leren; ergo: een mens is nooit te oud om te promoveren.
12. Met het ouder worden wordt alles slechter, behalve het vergeten (Jack Nieborg).
13. Openbaar vervoer: het vertrekt van een plek waar je niet bent en gaat naar een plek waar je niet moet zijn.

Joline Bosmans
25 november 2009

REHABILITATION ASPECTS OF AMPUTATION

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Voorwoord

"Amputatie, prothesiologie en orthesiologie (A&P)" is al van oudsher een speerpunt van het Centrum voor Revalidatie (CvR). Veel tijd, werk en energie zijn in dit speerpunt gestoken voor wat betreft onderzoek, onderwijs en patiëntenzorg, hetgeen geresulteerd heeft in diverse nationale en internationale publicaties en contacten, alsmede in een aantal dissertaties. Het is dan ook niet vreemd dat deze lijn zich steeds verder ontwikkelt, en dat een van de ontwikkelingen het opzetten en uitvoeren van een prospectief onderzoek naar fantoompijn en fantoomsensaties bij amputatiepatiënten was. Als 'oudere' fysiotherapeut heb ik de mogelijkheid gekregen niet alleen maar te zwoegen in de patiëntenzorg, maar ook te werken aan de eisen die tegenwoordig aan een fysiotherapeut in een universitair ziekenhuis worden gesteld. Aanvankelijk was ik nog aarzelend toen het ging over een promotieonderzoek ("Niemand moet er ongelukkig van worden en ik nog het minst."), maar op een bepaald moment heb ik toch de positieve keuze gemaakt voor het promotietraject, dankzij de steun, hulp en de positieve feedback van heel veel mensen in mijn (werk)omgeving.

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De beoordelingscommissie, bestaande uit prof. dr. J.H. Arendzen, prof. dr. J.W. Groothoff en prof. dr. J.S. Rietman, dank ik hartelijk voor hun tijd en bereidheid om dit proefschrift te lezen en te beoordelen.

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Arienne, grote zus, en Marianne, grote vriendin, fijn dat jullie mijn paranimfen wilden zijn. Jan Willem, bedankt voor de mooie omslag.
Mijn familie: het jonkie van de oudere generatie heeft het gefikst (toch wel een beetje trots?!); broers, zus, schoonzussen, nichten en neven – ik ben blij met jullie en met jullie interesse in mijn doen en laten.
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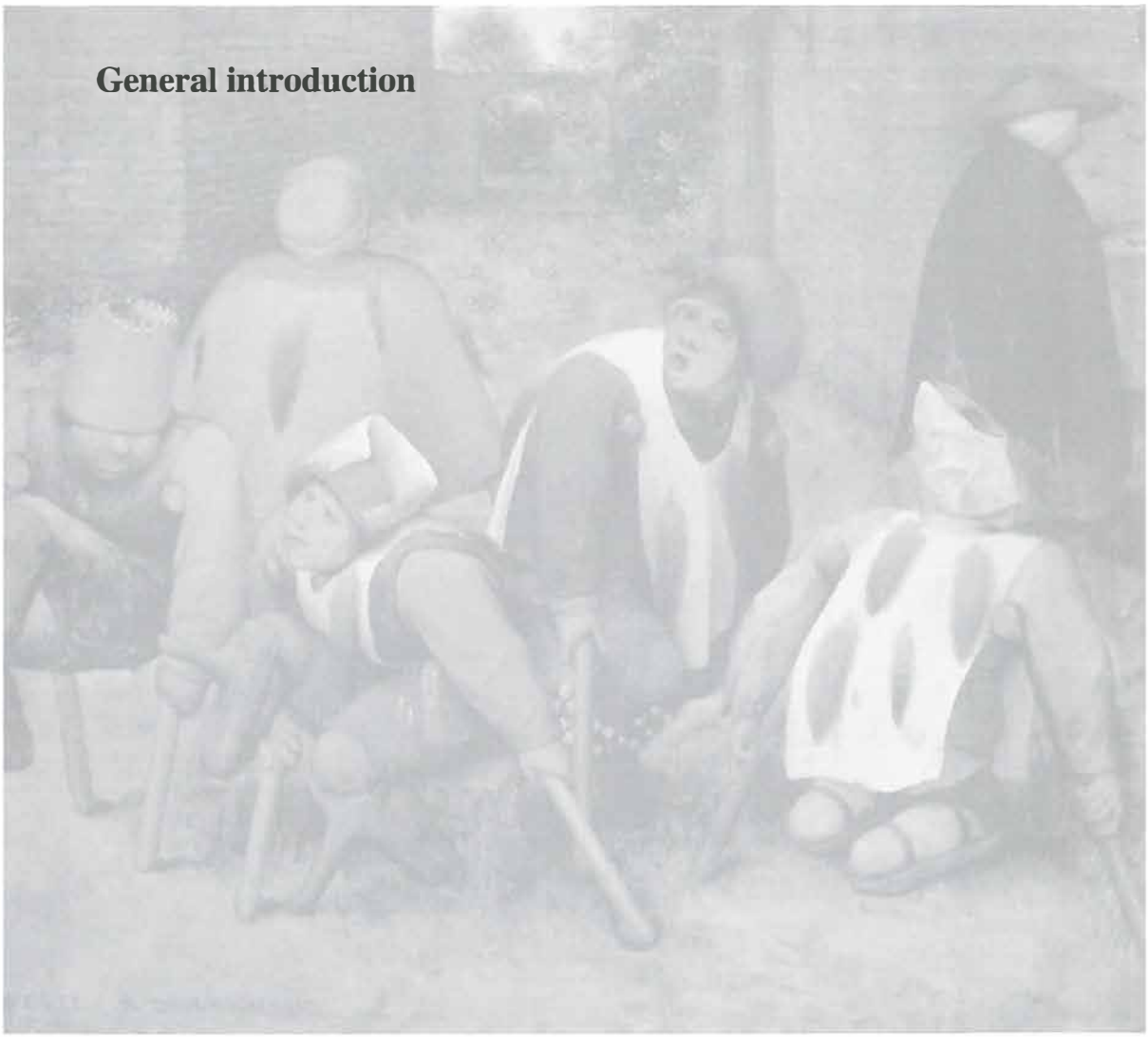
Contents

Chapter 1

General introduction



The first recorded case of a limb amputation and prosthetic replacement appeared in the book of the Rig-Vedas, written in Sanskrit in India between 3,500 and 1,800 B.C. The story reads that the leg of Warrior Queen Vishpla was amputated in battle. After the wound had healed, she was fitted with an iron leg, to enable her to walk and to return to the battlefield.

In early times, amputation was the consequence of a trauma, acts of war or of a punishment.[1,2] In the latter half of the fifth century B.C., a Greek author, possibly Hippocrates or Herodotus, described amputations for gangrene below the "boundaries of blackening". The amputation was to be performed as soon as the limb was "fairly dead and lost its sensibility".[3] In the 16th century, after a lengthy period of silence, amputation was described again as a surgical intervention, starting with Paré and Descartes.[2-6] No anaesthesia was used at the time, and this meant that timing was of the essence: the less time it took to perform an amputation, the better. The story goes that Liston (1794-1847), a well-known surgeon, needed only 2½ minutes to carry out an amputation. Once he accidentally amputated two fingers of an assistant, as well as the coat tails belonging to a spectator, while amputating a patient's leg at breakneck speed. The spectator dropped dead on the spot. Both the patient and the assistant died of hospital gangrene.[5,7] Liston also carried out the first amputation under ether anaesthesia in Europe, in 1846.

From around 1850 onwards, because of the use of anaesthesia (chloroform was introduced in 1851), and because of an improved knowledge of wound infections, it became possible for surgeons to focus their attention on improving amputation techniques and on determining the proper amputation level. The large number of great wars waged in the 19th and 20th century gave rise to great improvements in surgical techniques, and the possibilities for rehabilitation started to show a move towards increasingly sophisticated prosthetic limbs.

After an amputation, phantom (limb) pain and phantom (limb) sensations may occur. Phantom pain and phantom sensations, terms coined by Silas Weird Mitchell in the American Civil War (1861-1865), were not mentioned at all. Mitchell brought phantom pain and phantom sensations to the attention of the public at large by writing a fictitious autobiographic essay about these phenomena in serial form in *the Atlantic Monthly* in 1866.[8,9] "The case of George Dedlow" is still known all over the world. In the 20th century, descriptions of phantom pain and phantom sensations made their appearance in Erich Maria Remarque's novel

Im Westen nichts Neues[10], featuring a soldier who describes his own phantom limb sensations extremely graphically.

Phantom pain is an intriguing phenomenon, as are phantom sensations. Intriguing to the patient, as he feels something in a spot where nothing is there (any longer). And intriguing to the (para)medic, for why do some people experience sensations like these, whereas others do not (or do so to a lesser degree) and what can be done about them? To avoid any confusion it is necessary for patients, (para)medics and researchers to use the same terms in denoting these phenomena; hence, it is important to have a clear, uniform definition of phantom sensations and of phantom pain. After the amputation of an arm or a leg a patient may experience the sensation of the amputated, lost extremity still being there, the so-called phantom limb sensation.[11] The patient may also have the feeling that the amputated extremity has a different shape, the amputated part may seem to be in a different position or may seem to move, itch, tingle, or may seem to be feeling warm or cold. If any phantom sensation in the amputated part of the limb is so intense that it is experienced as pain, it is defined as phantom limb pain.[12] Phantom pain should be distinguished from stump pain. The latter is defined as pain in the amputation stump, so in the end of the part of the limb that is still there.[12] These phenomena may not only occur after the amputation of an extremity, but also after the amputation of a breast or other body parts, as well as after dental or surgical procedures such as tooth extraction, root canal therapy or root tip amputation.

So, although phantom pain and phantom sensations were well-known phenomena, they were often regarded as a psychiatric illness, until well into the 20th century, and in the USA especially; patients were not taken seriously at all and were fobbed off with the statement that the pain was "just in their heads".[13] For that reason, patients were afraid to indicate that they were suffering from phantom pain and/or phantom sensations. As a result, in medical literature a reported rate of phantom pain of 0.5 to 10% was the accepted norm.[11]

After the Second World War large research projects on amputation and prostheseology were started up in various countries, in which amputation techniques were examined and through which prosthetic research received a new impetus. From the 1970s' onwards research was done on other aspects of amputation as well, like risk factors of phantom pain and phantom sensations[14,15], prevention of phantom pain[15-17], stump problems/skin problems after amputation[18,19], survival/mortality after amputation[20-24], functional outcome after amputation[25-29], quality of life/subjective well-being of amputees[30] and sexuality

after amputation.[31] Actually, from the moment the medical world started to spend time, money and interest on research, amputees have been taken more seriously and more attention has been paid to amputees' questions.

The Department of Rehabilitation Medicine of the University Medical Centre Groningen has already performed various studies on different aspects of amputation.[18,19,31-38] However, these studies again raise new questions about the different aspects of amputations. In chapters 2 through 8 of this thesis a number of these questions will be investigated and answered.

Cross-sectional research has shown that patients having undergone a traumatic amputation are usually younger than other amputees, that the former are usually still alive after a long period, hence making up an important part of the research population. However, at present most amputations are done on patients suffering from peripheral vascular disease: patients who are elderly and in weaker health, and who do not have a long life expectancy. It would seem that these differences in age and perspective cause a bias in the research data. In chapter 2 bias in amputation research is investigated.

One of the phenomena occurring after an amputation, is phantom (limb) pain. As mentioned earlier, in medical literature a reported rate of phantom pain of 0.5% to 10% used to be the accepted norm. Should a clinician keep propagating this (low) norm, keeping quiet about the pain, then this will probably result in amputees keeping quiet about their phantom pain, giving low prevalence rates. In later studies prevalence and incidence rates of phantom pain for all limb amputees range considerably (41% to 85%). But should a clinician be receptive to the amputee's pain, and clearly define what phantom pain is, then this will probably result in more realistic figures emerging. Besides, one should ask oneself whether amputees suffering from phantom pain a couple of times per year, may be compared to amputees suffering from phantom pain on a daily basis, or all the time. In literature there is usually no indication whether these people are all thrown together or whether a distinction has been made between the different groups. In chapter 3 the consequences for the prevalence rate of phantom pain, when different cut-off points for the frequency of phantom pain are applied, are investigated.

Questions like: "What is the cause of bias in amputation research?" and "What is the prevalence rate of phantom pain?" may offer a large amount of numerical data regarding the prevention of phantom pain, phantom sensations and stump pain, but they offer no information whatsoever about what phantom pain means to the

amputee. In chapter 4 the impact of an amputation and of phantom pain on the subjective well-being of amputees is investigated in a qualitative study using a new socio-medical model.

Until now, few prospective studies have been done on phantom pain, and the research that has been done only featured a follow-up time of 2 years at most. Most studies were cross-sectional or retrospective, making cause-effect relationships between determinants and phantom pain difficult. In chapter 5 determinants for phantom pain are investigated in a prospective multicentre cohort study.

A special type of amputation is the knee disarticulation. It is claimed to offer a considerable walking stability (and so a better mobility), with a limited mortality. In chapter 6 this clinical claim is investigated in a historical cohort study performed in the hospital of Drachten.

Walking ability is an important factor in ADL independence. For lower limb amputees, the ability to walk and the ability to cover a reasonable distance are of major importance in retaining independence and social mobility. Especially elderly amputees are often limited in their walking ability because of comorbidity such as diabetes mellitus, osteoarthritis or vascular disease. In chapter 7 different factors influencing the ability to walk a distance of 500 metres or more are investigated.

In the course of time, many amputees are fitted with one or more prostheses. This fitting is done in prosthetics and orthotics facilities that offer other services as well. Consumers of prosthetics and orthotics facilities do not only require the very best device, nowadays, their satisfaction with the service of the facilities is very important, too. The facilities have to keep asking themselves the question whether their service is still up-to-date, and whether improvements should be made. In chapter 8 consumer satisfaction with different prosthetics and orthotics facilities is investigated and compared with the results of a similar study performed in 2002.

Finally, in chapter 9, the clinical implications of this thesis are discussed, followed by recommendations for future research on the different topics.

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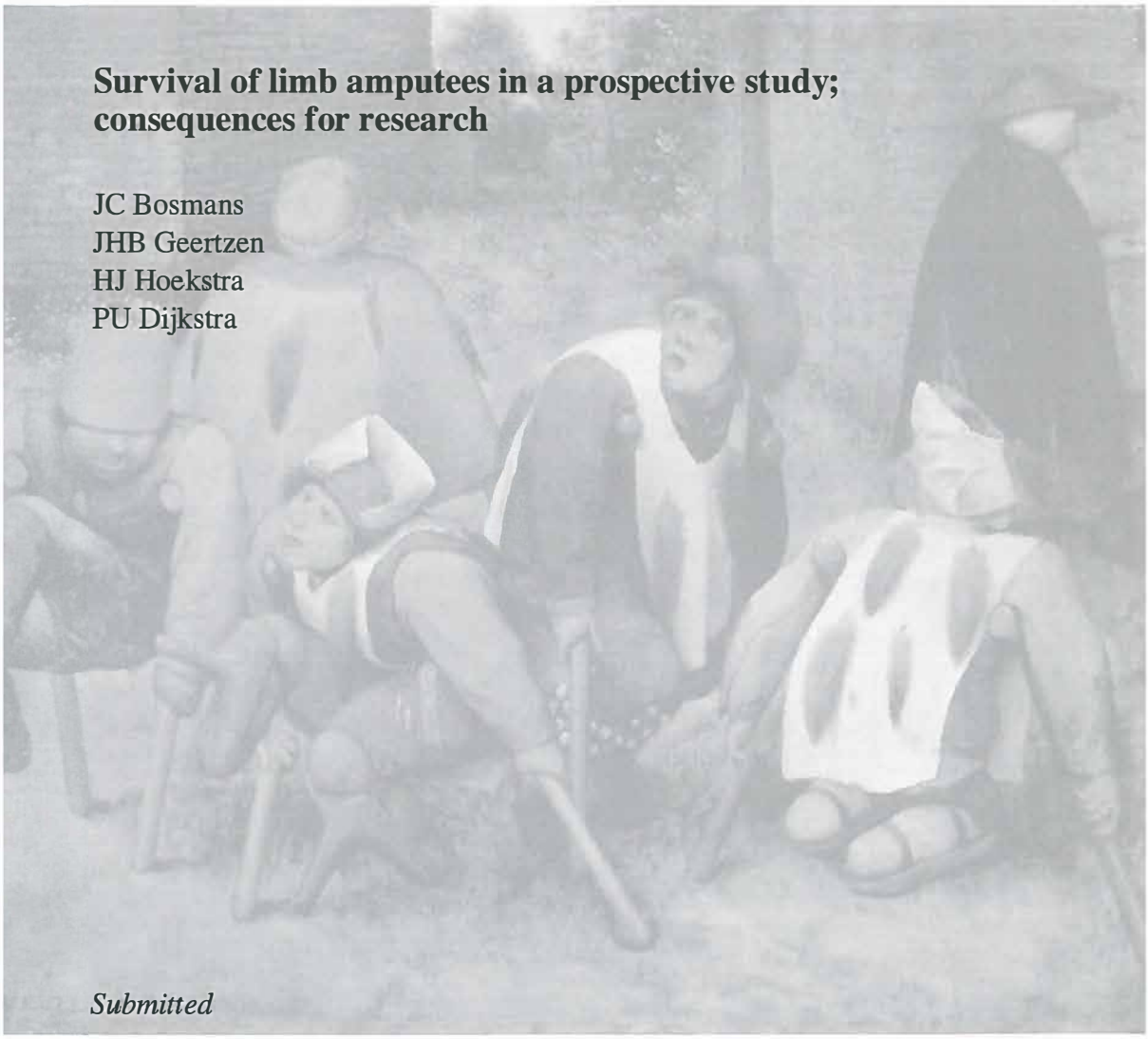
Chapter 2



Survival of limb amputees in a prospective study; consequences for research

JC Bosmans
JHB Geertzen
HJ Hoekstra
PU Dijkstra

Submitted

Abstract

The study analysed the survival rate of patients who were referred to a prospective, multicenter cohort study, and the differences between participants and non-participants. In total, 214 patients were referred, of whom 63% (n=134) participated in the prospective study by questionnaires; the others (non-participants) were followed over time through records. Reason for amputation was a peripheral vascular disease (PVD) for 67% (n=90) of the participants and 83% (n=66) of the non-participants. The mean survival time of the participants and non-participants was 36.1 and 27.1 months, respectively. Within PVD the mean survival time of participants and non-participants was 34.4 and 24.5 months, respectively. Sixty percent of the patients referred survived in the 4-year period after amputation. More participants (68%) survived, as compared to non-participants (44%). In conclusion, insight into the survival rates in a prospective study on patients scheduled for a limb amputation is given. Our study sample is biased by selection and death. Participants are in better general health than non-participants.

Introduction

It is common knowledge, both from daily practice and from literature, that the survival rate after a limb amputation is low, especially in patients with an amputation due to vascular problems. Historical cohort studies show that the survival rate after a lower-limb amputation is moderate in the course of time.[1-12] Consequences of the moderate survival rates for amputation research are hardly ever reported. In research one wants to generalise the results of the study to the target population. To be able to do so, the target population must have the same properties as the research population from which the research sample was drawn.
Prospective studies on phantom sensations and phantom pain after a lower-limb amputation seldom report inclusion and exclusion criteria, referral rates and drop-out rates (death included) of the patients under study.[13-20] Thus, in these studies little is known about bias through drop-out or death. Studies concerning predictors for functional outcome or quality of life after a lower-limb amputation usually include patients with a better physical condition than the patients not included, and as a rule they, too, seldom report their inclusion and exclusion criteria and inclusion and drop-out rates.[21-27] Hence, in amputation research selection bias in study samples has certainly occurred but has seldom been quantified. A consequence of this selection is that amputees who manage to reach the prosthetic stage of the rehabilitation process are a smallish subset of those who have had an amputation, and they are in a better physical health.
In 2003 a 4-year prospective, multicenter cohort study on phantom pain, phantom sensations and stump pain after a limb amputation was initiated at the University Medical Center Groningen (UMCG). During that prospective study a substantial number of patients referred did not fulfill inclusion criteria and, as a consequence, became non-participants.
The aim of the current study was to analyse the survival rate of patients who were referred to this multicenter study, and to analyse the differences between participants and non-participants.

Methods

Patients

Patients were recruited for a prospective study in which people scheduled for a limb amputation were referred by vascular surgeons and surgeons of the departments of surgical oncology, traumatology, orthopedic surgery, and plastic and reconstructive surgery, in one university hospital and five general hospitals in the Northern Netherlands between November 2003 and May 2007. Inclusion criteria for the prospective study were: (1) the scheduled amputation had to be due to either a peripheral vascular disease with or without diabetes mellitus (DM), an ulcer or an infection (PVD), or cancer, or a trauma or complex regional pain syndrome type I (CRPS I), (2) the amputation level had to be through the metacarpal phalangeal joints or metatarsal phalangeal joints or more proximal, (3) the amputation had to be the first amputation of the extremity, (4) patients had to have a minimum age of 18 years, (5) patients had to have the possibility to fill in the first questionnaire before the amputation or five days after the amputation at most, and (6) patients had to have a sufficient command of spoken and written Dutch to be able to fill in questionnaires.

Medical ethical committees of all hospitals participating approved the study protocol.

Data entry

Patients' characteristics, the reason for, and the level and date of amputation were recorded. Lower-limb amputations were categorised into distal (transtibial, ankle or foot), knee disarticulation or proximal (pelvis, hip or transfemoral). Upper-limb amputations were categorised into distal (forearm or wrist) or proximal (forequarter, shoulder or upper arm); no elbow disarticulations were performed. If patients underwent a second amputation of the same extremity during the study period, the date of the first amputation was used for statistical analyses. If a patient died during the follow-up, a note was made of the date of death. On 1st November 2007, the survival rate of all patients referred was investigated by analysing their records kept by the participating hospitals or by consulting the patients' general practitioners.

Participants were patients who filled in questionnaires over time and non-participants were followed over time through their records.

Detailed outcomes of the prospective study will be reported elsewhere (Determinants of phantom limb pain, Bosmans JC, Geertzen JHB, Post WJ, van der Schans CP, Dijkstra PU, submitted)

Statistics

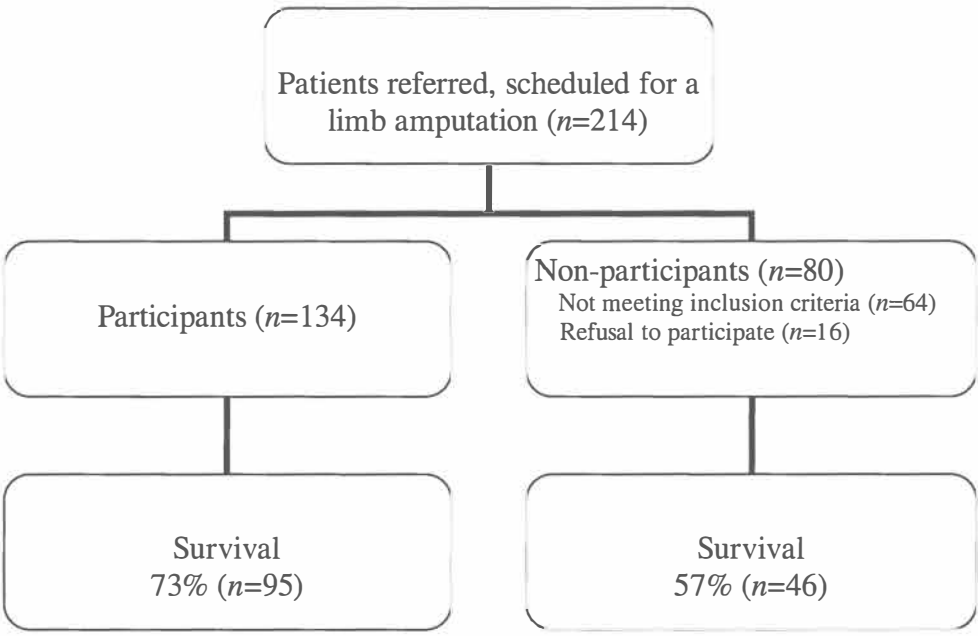
Statistical analyses were carried out in SPSS 16.0 for Windows, using descriptive statistics. Differences between the participants and non-participants were analysed using t-tests for independent samples and χ^2-tests as appropriate. Kaplan-Meier survival curves were drawn for the participants and non-participants and log rank tests were carried out. P values ≤ 0.05 were considered to be statistically significant. Data will be presented in tables enabling detailed comparison with literature data, as well as in figures providing an overview of events over time.

Results

Participation of patients

In total, the data of 214 patients referred were available. Of these patients 134 were followed longitudinally (participants) by means of questionnaires during a maximum of 4 years, while 80 patients were non-participants and were only followed over time through their records (16 patients refused to participate and 64 patients did not meet the inclusion criteria (46 patients because of comorbidity, 9 because it was not the first amputation and 9 patients because the time interval between amputation and the first questionnaire exceeded five days)) (figure 1).

Figure 1 Flow diagram of patients referred.



The patients' characteristics, the reason for and level of amputation, and the number of patients who died during the study, are summarised in table 1. No significant differences were found in sex (p=0.696) and level of amputation (p=0.462) between participants and non-participants. Non-participants were generally older than participants (p=0.074). More non-participants (83%) had an amputation due to PVD, as compared to participants (67%), whereas participants more often had an amputation due to trauma or CRPS I, or cancer (p=0.033). Within the group of patients who had an amputation because of PVD no significant differences in age between the non-participants (mean: 71 yrs, sd: 12.9, n=66) and participants (mean 67 yrs, sd 13.3, n=90) were found (p=0.080). Significantly more participants survived, as compared to non-participants (p=0.018) (table 1).

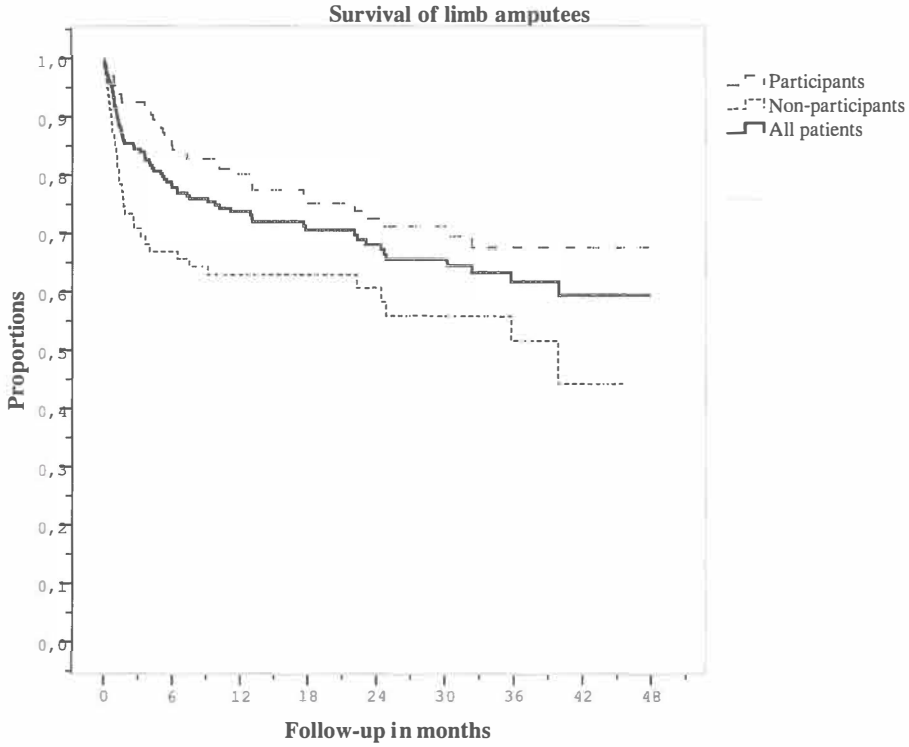
Table 1 Characteristics, reason for and level of amputation, and number of deaths during the study of participants and non-participants with a limb amputation.

	Participants (n=134)	*Non-participants (n=80)*	*Significance of the difference between participants and non-participants*
Sex, % (*n*)			p=0.696
Female	37% (50)	40% (32)	
Male	63% (84)	60% (48)	
Age, Mean (sd)	62.0 yrs (16.72)	66.0 yrs (18.03)	p=0.074
Amputation reason, % (*n*)			p=0.033
PVD	67% (90)	83% (66)	
Cancer	13% (18)	10% (8)	
Trauma or CRPS I	19% (26)	7% (6)	
Amputation level, % (*n*)			p=0.462
Proximal amputation	30% (40)	38% (30)	
Knee disarticulation	15% (20)	11% (9)	
Distal amputation	55% (74)	51% (41)	
Survival during study, % (*n*)	73% (95)	57% (46)	p=0.018

Reasons for amputation were either a peripheral vascular disease with and without diabetes mellitus, an ulcer, an infection (PVD), or cancer, or trauma or complex regional pain syndrome type I (CRPS I). Levels of amputation of the lower limb were either proximal (pelvis, hip or transfemoral) or knee disarticulation (KD) or distal (transtibial, ankle or foot). Levels of amputation of the upper limb were either proximal (forequarter, shoulder or upper arm) or distal (forearm or wrist).

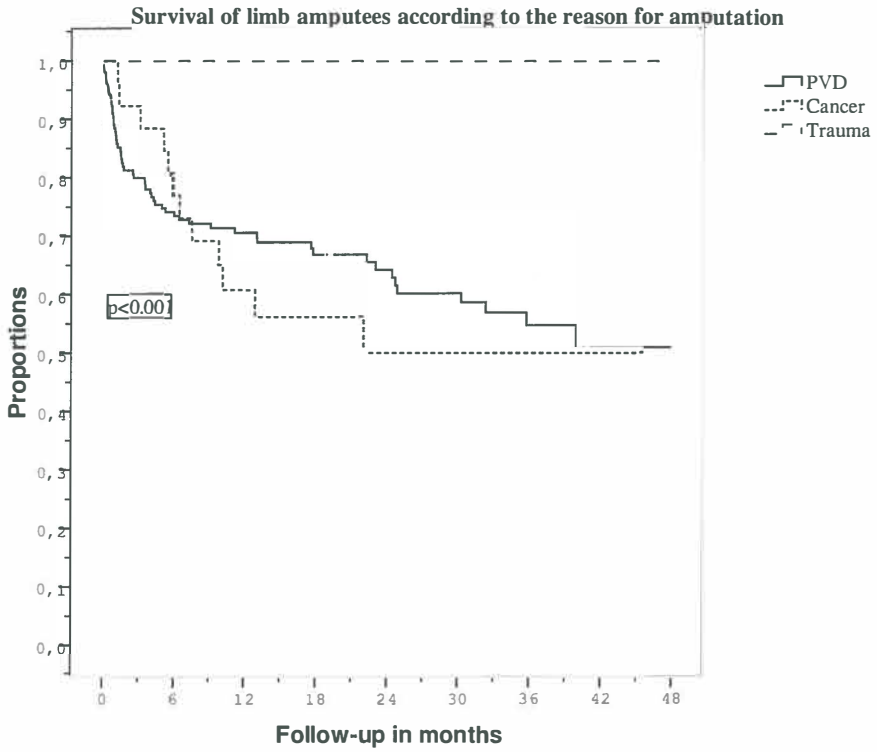
The mean survival time of participants (36.1 months) was significantly longer than that of non-participants (27.1 months) (logrank test p=0.005) (figure 2).

Figure 2 Kaplan-Meier survival curves of all patients (n=214), participants (n=134) and non-participants (n=80).



Of the patients who had an amputation due to PVD (98 out of 156) or cancer (14 out of 26) 62% survived, while all patients who were amputated because of a trauma or CRPS I survived (32 out of 32) (logrank test p<0.001) (figure 3). Within the group of amputees because of PVD the mean survival time of participants (34.4 months) was longer than that of non-participants (24.5 months) (logrank test p=0.010).

Figure 3 Kaplan-Meier survival curves of all limb amputees according to the reason for amputation (PVD (n=156), cancer (n=26), or trauma or CRPS I (n=32). The difference in survival between trauma patients on the one hand and PVD and cancer patients on the other hand was significant (p<0.001).



After a proximal amputation the mean survival time of patients was 29.2 months, after a knee disarticulation 35.5 months and after a distal amputation 34.5 months (logrank test p=0.250) (figure 4). Detailed 4-year survival data of all amputees, categorised according to sex, reason for and level of amputation, are presented in table 2.

Within the group of amputees 7% (n=14) had had an upper-limb amputation, this being proximal in 71% (n=10) of the patients. The main reason for upper-limb amputation was a trauma or CRPS I (71%, n=10). One of the participants with an upper-limb amputation died 6.5 months after his amputation due to cancer.

Figure 4 Kaplan-Meier survival curves of all limb amputees according to the level of amputation (proximal leg = pelvis, hip or transfemoral and proximal arm = forequarter, shoulder or upper arm (n=70), knee disarticulation (n=29), or distal leg = transtibial, ankle or foot and distal arm = forearm or wrist (n=115)).

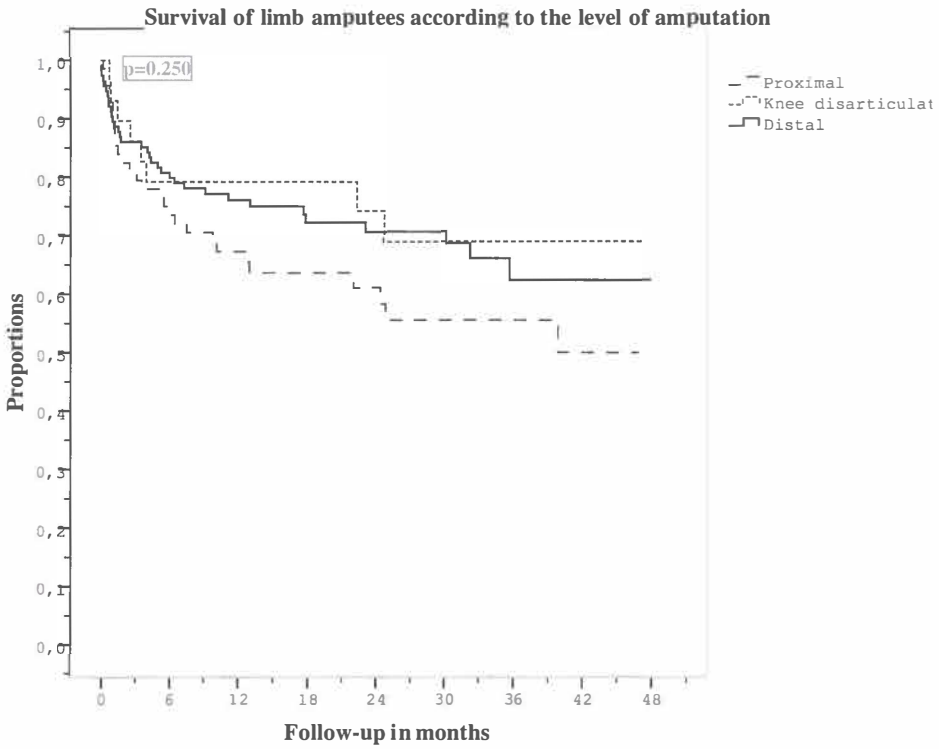


Table 2 Survival rates in percentages and exact numbers (*n*) of limb amputees in the current study on the basis of Kaplan-Meier analyses for all patients referred, according to sex, reason for and level of amputation.

	6 months	*1 year*	*2 years*	*3 years*	*4 years*
All limb amputees (214)	78% (168)	74% (159)	68% (151)	62% (145)	60% (144)
Participants (134)	85% (114)	80% (108)	73% (101)	68% (98)	68% (98)
Non-participants (80)	67% (54)	63% (51)	61% (50)	52% (47)	44% (46)
Sex					
All limb amputees					
Male (132)	79% (104)	72% (96)	64% (89)	61% (87)	57% (86)
Female (82)	78% (64)	77% (63)	75% (62)	65% (58)	65% (58)
Reason for amputation					
All limb amputees					
PVD (156)	74% (116)	71% (111)	64% (105)	55% (99)	51% (98)
Cancer (26)	77% (20)	61% (16)	50% (14)	50% (14)	50% (14)
Trauma or CRPS I (32)	100% (32)	100% (32)	100% (32)	100% (32)	100% (32)
Level of amputation					
All limb amputees					
Proximal (70)	74% (52)	67% (48)	61% (45)	56% (43)	50% (42)
Knee disarticulation (29)	79% (23)	79% (23)	74% (22)	69% (21)	69% (21)
Distal (115)	81% (93)	76% (88)	71% (84)	63% (81)	63% (81)

Discussion

The results of the current study confirm a moderate survival rate of patients after a limb amputation. Of the participants in this study a larger percentage (73%) survived, as compared to the non-participants (57%).

As already stated, in research one wants to generalise the study results to the target population. To be able to do so, the research sample must be a random sample from the target population. Looking at the survival rates of the participants and non-participants found in the current study, it is clear that a bias in population has occurred. When the survival rates of the current study are compared to those of other prospective studies on amputation and phantom pain, one encounters the problem that only the survival of included patients is reported, as a rule. The reported survival rate ranges from 59% to 92%, 6 months after amputation[13-15,17-20], and between 59% to 67% 12 months after amputation.[15,16,18-20] In only one study a two-year follow-up was given[14]; the survival rate was 59%. The numbers of amputees participating in those prospective studies were relatively small (n=21 to n=60). Those studies mainly included patients amputated because of PVD, a group

of amputees having a large chance of dying relatively soon after the amputation. Furthermore, those studies seldom provide an insight into the number of patients referred to the study, the number of patients excluded and the reasons for exclusion, and drop-out by death.[13-17,20] Only Nikolajsen et al[18,19] report the number of patients scheduled for an amputation, the number of patients excluded and the reasons for exclusion, and the number of drop-outs (death included). Other authors report either the number of drop-outs[17,20] or the reason for excluding patients[13-17] or the number of patients excluded.[17] As a consequence, survival data from our current study cannot be compared adequately to those studies. However, from the data in studies by Nikolajsen *et al*[18,19], one can deduce that at least 44% of the excluded patients were in poorer general health than the patients included. In other studies it has not been made clear how many patients were excluded for reasons of a poor general health.

In a prospective study concerning predictors for functional outcome after a limb amputation, excluding severely disabled patients, a survival rate of 85% within the first year was found.[23] Primarily, patients who went to a nursing home died, probably because those patients were in a poor general health. Maybe as a result of the exclusion criteria of that study, viz. not being able to understand the test instructions and being severely disabled without any walking ability before the amputation for reasons not related to PVD, the survival rate in that study was high compared to that in other prospective studies.[23] In cross-sectional studies concerning functional outcome after a limb amputation, survival rates were not an issue because only survivors could be selected.[21,22,24-28] Additionally, explicit inclusion or exclusion criteria for those studies were seldom specified, except that the patients had to have undergone a lower-limb amputation and had been referred for a limb fitting, those patients forming a convenience sample more or less.

In historical cohort studies an estimation of the survival rates after amputation is obtained from historical data, usually from different sources (databases), hospital records, medical insurance databases and from Central Person Register databases. The total number of patients amputated is known and the number of deaths is recorded as a matter of course.

In certain historical cohort studies the 1-year survival rates range from 49% to 73%[1,2,4,8,10,12,29] and the longer term (interval 5-year) survival rates are 26%.[1,2,12] The number of patient records in these historical cohort studies was large (n=174 to n=21,520).[1,2,4,6,8-11,29]

The limitation of the current study is that the number of referred patients scheduled for a lower-limb amputation was considerably smaller than expected. On the basis of earlier Dutch amputation studies[3, 21], the population of the Northern Netherlands (comprising the provinces of Groningen, Friesland and Drenthe)[30] and the number of participating hospitals, it was estimated that each year 150 to 170 new patients with a lower-limb amputation could be referred to the current study. Despite all efforts, only 34 to 38% (n=200, inclusion period 3½ years) of the estimated population of lower-limb amputees in the Northern Netherlands were referred, indicating a considerable selection bias. Selection bias has probably not occurred for upper-limb amputees. Of the 214 referred patients, 14 patients were scheduled for or had undergone an upper-limb amputation (through wrist or more proximal) of whom 10 patients had had a trauma or CRPS I. This means an incidence of 0.2/100,000 in the Northern Netherlands. Our rate corresponds with the incidence rate of traumatic upper-limb amputations in Sweden, Norway and the USA, where rates of 0.1, 0.1 and 0.4 /100,000 inhabitants, respectively, have been reported.[31-33]
In the Northern Netherlands patients with an upper-limb amputation are mainly treated at the UMCG.
A recommendation for future research is that inclusion and exclusion criteria, and referral rates are reported more clearly.
In conclusion, insight into the survival rates in a prospective study on patients scheduled for a limb amputation is given. Our study sample of patients is biased by selection and death. Participants are in better general health than non-participants.

Acknowledgments

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Chapter 3

Phantom pain: a sensitivity analysis

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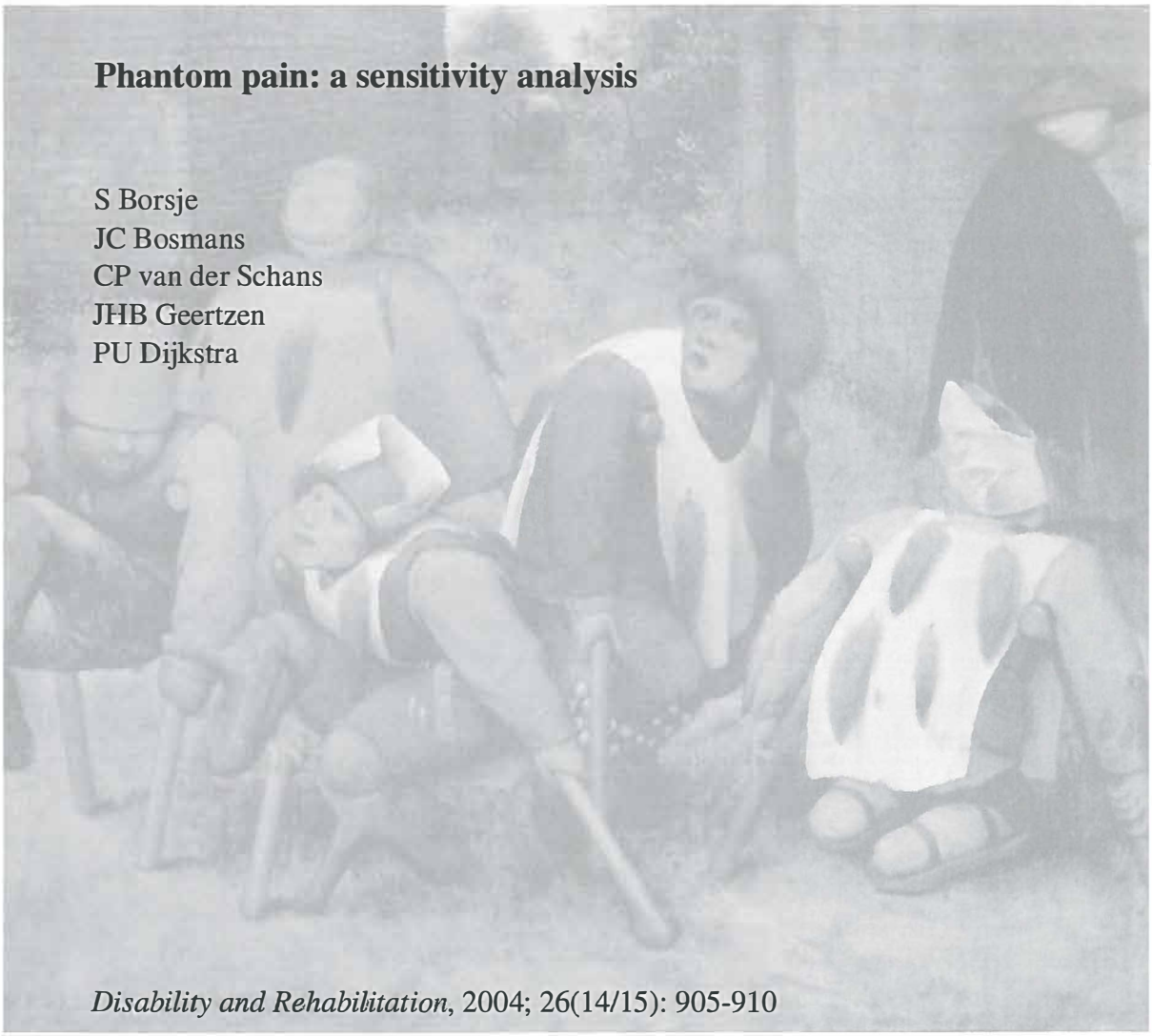

Disability and Rehabilitation, 2004; 26(14/15): 905-910

Abstract

Purpose: To analyse how decisions to dichotomise the frequency and impediment of phantom pain into absent and present influence the outcome of studies by performing a sensitivity analysis on an existing database.
Methods: Five hundred and thirty-six subjects were recruited from the database of an orthopaedic workshop and filled out a questionnaire in which the following items were assessed: demographics, side, date, level and reason for amputation, presence and frequency of phantom sensations, phantom pain and stump pain, and impediment due to phantom pain.
Results: The prevalence of phantom pain ranged from 9-72%[§] when different cut-off points for the frequency of phantom pain were applied. The significance of the various risk factors for the prevalence of phantom pain changed when different cut-off points were applied. Only stump pain and phantom sensations were significant risk factors for all cut-off points. Risk factors for the impediment of phantom pain changed when different cut-off points were applied and these risk factors were different from those for the prevalence of phantom pain.
Conclusion: The choice of cut-off points influences the outcome of phantom pain studies considerably. This study provides some insight into the differences in prevalence and risk factors found in literature.

[§] Accidentally, in the original abstract of the article 7% instead of 9% was reported.

Introduction

Phantom sensations, phantom pain and stump pain (or residual limb pain) are common phenomena after an amputation of an extremity. Phantom sensations are defined as all non-painful sensations in the amputated part of the extremity. Phantom pain is defined as any phantom sensation that is so intense that it is experienced as painful. Stump pain (residual limb pain) is defined as any painful sensation localised in the stump.[1]

Several risk factors have been associated with phantom pain including pre-amputation pain, gender, time elapsed since amputation, phantom sensations, stump pain, amputation level and prosthesis use.[2-13] Pre-operative extremity pain is found to be a risk factor for immediate postoperative phantom pain, but not for phantom pain in the long-term.[3,4] It has been found that women report a higher intensity of phantom pain compared to men and that a greater percentage of women experienced phantom pain.[5,6] However other studies did not find such a relationship between phantom pain and gender.[3] When time passes phantom pain may diminish.[3,7,8] Nikolajsen *et al.*[4] only support this finding partially; they found that the prevalence of phantom pain did not decline with time, but the duration of the pain attacks diminished significantly. Other studies did not find a relationship between phantom pain and time elapsed since amputation at all.[9,10] For upper extremity amputation as well as for lower extremity amputation there is a strong interrelationship between phantom sensations, stump pain and phantom pain.[1,3,4,11]

From a theoretical point of view it can be hypothesised that phantom pain may be related to prosthetic use. A phantom which does not fit the prosthesis might be very awkward. However, most studies showed no relationship between phantom pain and the use of a prosthesis.[9,12] Only the use of a myoelectrical prosthesis might prevent phantom pain.[13]

The reported prevalence rate of phantom pain differs considerably between studies, ranging from 49-82%.[1-3,7,8,11,12,14,15] This variation may be attributed to differences in assessment method, selection of study population, definitions of phantom pain or a lack of distinction between phantom sensations, phantom pain and stump pain.[1,2] It is also possible that the choice of cut-off points for frequency of phantom pain and experienced impediment due to phantom pain may be one of the factors that contribute to the variation in prevalence found.[1,2,5,8,9,11,12,16-18] Additionally, it is possible that these cut-off points also influence the outcome of studies with respect to risk factors for phantom pain.

The aim of this study is to analyse how decisions to dichotomise the frequency and impediment of phantom pain into absent and present influence the outcome of studies by performing a sensitivity analysis on an existing database.

Methods

Sample and procedure

Subjects with an upper or lower extremity amputation were recruited from the database of an orthopaedic workshop (OIM, Haren, the Netherlands). This database consists of subjects who were referred to the orthopaedic manufacturer for the fitting of a prosthesis. These subjects were sent a letter, which requested their participation in this study. Subjects who answered affirmatively were sent the questionnaire. Of the 1556 people approached 632 were willing to participate in this study. Eventually, 536 subjects returned the questionnaire. Of these 536 subjects 99 had an amputation of the upper extremity, of whom one had a bilateral amputation and 437 subjects had an amputation of the lower extremity, of whom 44 had a bilateral amputation. Demographics and characteristics of the amputations are listed in table 1.

Instruments

The questionnaires used were The Groningen Questionnaire Problems after Arm Amputation (GQPAA) or The Groningen Questionnaire Problems after Leg Amputation (GQPLA).[1,2,19] These questionnaires were developed because of a lack of existing valid and reliable Dutch questionnaires assessing phantom sensations, phantom pain and stump pain. These questionnaires are partially based on two English questionnaires[8,9] and the questionnaire used by the Dutch Working Group of Users of Lower Limb Prostheses, enabling comparison with previous surveys. Besides demographic questions these questionnaires assess the presence and frequencies of phantom sensations, phantom pain and stump pain, and impediment subjects experienced due to phantom sensations, phantom pain and stump pain. In previous studies these questionnaires have been described in detail.[1,2,19] Frequency of phantom pain was assessed as never, few times a year, few times a month, few times a week, few times a day, few times an hour or always. The impediment due to phantom pain was classified as none, hardly any, moderate, much or very much.

Statistical analysis

Statistical analysis was performed by using the SPSS version 10.0 for Windows. Factors significantly associated with phantom pain were identified by means of chi-square analysis and *t*-test for independent samples. A *p*-value ≤ 0.05 was considered significant. No continuity correction is reported unless in the chi-square analysis the *p*-value changed from significant into not significant when applying continuity correction.

Frequency of phantom pain was dichotomised (absent or present) using five different cut-off points. Cut-off points for the frequency of phantom pain (Fpp) were (a) none, (b) a few times a year, (c) a few times a month, (d) a few times a week, (e) a few times a day, (f) a few times an hour and (g) always.

Fpp1: absent	= a	present = a few times a year or more (b-g)
Fpp2: absent	= a-b	present = a few times a month or more (c-g)
Fpp3: absent	= a-c	present = a few times a week or more (d-g)
Fpp4: absent	= a-d	present = a few times a day or more (e-g)
Fpp5: absent	= a-e	present = a few times an hour or more (f-g)

The groups 'a few times an hour' and 'always' were grouped together because otherwise the groups would be too small to analyse separately with statistical power.

The impediment subjects experienced due to phantom pain was also dichotomised (absent or present) using four different cut-off points. Cut-off points for the impediment (Ipp) subjects experienced were (a) none, (b) hardly any, (c) moderate, (d) much and (e) very much.

Ipp1: absent = a	present = b-e
Ipp2: absent = a-b	present = c-e
Ipp3: absent = a-c	present = d-e
Ipp4: absent = a-d	present = e

Subsequently the following factors were analysed for an association with the frequency of phantom pain and impediment experienced: age at time of amputation, time elapsed since amputation, reason for amputation (vascular/diabetes mellitus or other), gender, phantom sensations (present or absent), stump pain (present or absent), bilateral amputation (yes or no), extremity

(arm or leg), proximal or distal amputation (proximal: proximal or through elbow/knee; distal: distal elbow/knee). A correlation coefficient was calculated to measure the degree of association between the frequency of phantom pain and the impediment subjects experience. All statistical analyses were performed on valid responses.

Table 1 Characteristics of patients, amputations, frequency of experienced phantom pain and experienced impediment due to phantom pain.

Variables	*Descriptives*
Age in years, mean (sd)	61.5 (18)
	Percentage (*n*)
Gender	
male	69.4% (372)
female	28.5% (153)
Extremity	
upper	18.5% (99)
lower	81.5% (437)
Amputation level	
through or above knee/elbow	37.7% (202)
below knee/elbow	61.2% (328)
Amputation reason	
trauma	38.4% (206)
vascular disease	23.7% (127)
diabetes	16.8% (90)
cancer	9.1% (49)
congenital	6.9% (37)
other	4.3% (23)
Bilateral	8.4% (45)
Frequency of experienced phantom pain	
never	24.8% (133)
a few times a year	16.6% (89)
a few times a month	17.5% (94)
a few times a week	10.6% (57)
a few times a day	10.1% (54)
a few times an hour or more	1.9% (10)
always	5.8% (31)
Impediment due to phantom pain	
none	4.5% (24)
hardly any	18.1% (97)
moderate	21.6% (116)
much	18.5% (99)
very much	4.5% (24)

Note that the totals in the table do not equal 536 because not all subjects completed the entire questionnaire.

Results

The frequency of experienced phantom pain and the impediment due to phantom pain are listed in table 1. The prevalence (frequency) of phantom pain that is found after applying different cut-off points is shown in figure 1. The prevalence rate ranged from 9-72%. The reported impediment rate due to phantom pain for the different cut-off points ranged from 7-93% (figure 2). The relationships between phantom pain and the different risk factors are listed in tables 2 and 3. The significance of the relationship of different risk factors for phantom pain changed after applying different cut-off points. For instance, extremity (upper or lower extremity) was a significant risk factor for phantom pain for two of the five cut-off points whereas stump pain and phantom sensation were significant risk factors for phantom pain for all cut-off points (table 3).

Figure 1 Percentage of subjects reporting phantom pain (prevalence) for different cut-off points.

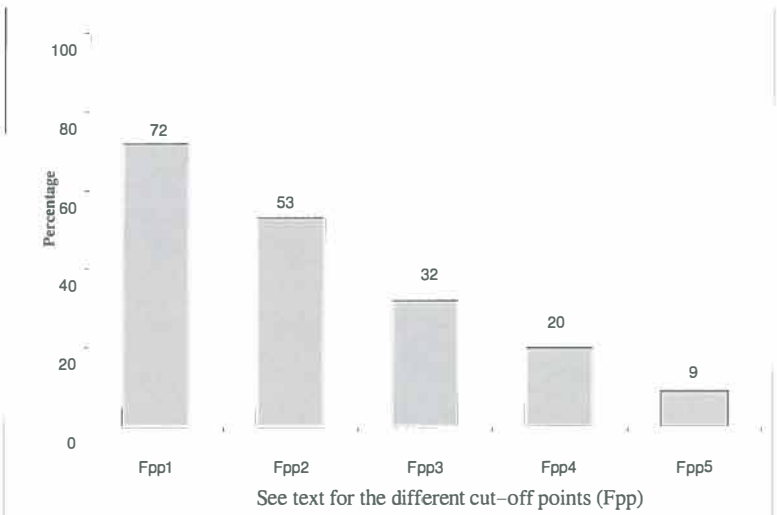

Table 2 The relationship between the prevalence (frequency) of phantom pain and the age at time of amputation and time elapsed since amputation for different cut-off points.

Phantom pain	*Yes: mean (SD)*	*No: mean (SD)*	*Mean difference*	P-*value*
Age at time of amputation (years)				
Fpp1: few times a year	48.1 (22.4)	31.3 (23.0)	–16.8	0.867
Fpp2: few times a month	**50.9 (21.3)**	**35.2 (23.7)**	**–15.7**	**<0.001**
Fpp3: few times a week	52.1 (22.4)	39.7 (23.3)	–12.4	0.298
Fpp4: few times a day	50.2 (22.9)	42.1 (23.6)	–8.2	0.456
Fpp5: few times an hour	49.0 (23.4)	43.2 (23.7)	–5.8	0.737
Time elapsed since amputation (years)				
Fpp1: few times a year	**15.8 (16.0)**	**25.8 (20.2)**	**10.0**	**<0.001**
Fpp2: few times a month	**13.6 (14.6)**	**24.1 (19.3)**	**10.4**	**<0.001**
Fpp3: few times a week	**12.9 (15.5)**	**21.1 (18.0)**	**8.3**	**<0.001**
Fpp4: few times a day	15.8 (17.5)	19.0 (17.6)	3.2	0.953
Fpp5: few times an hour	18.9 (19.3)	18.3 (17.5)	–6.1	0.163

Results of *t*-test for independent samples. In bold type: *p*: significance ≤0.05.
See text for the calculation and definitions of the different cut-off points.

Figure 2 Percentage of subjects reporting impediment due to phantom pain for different cut-off points.

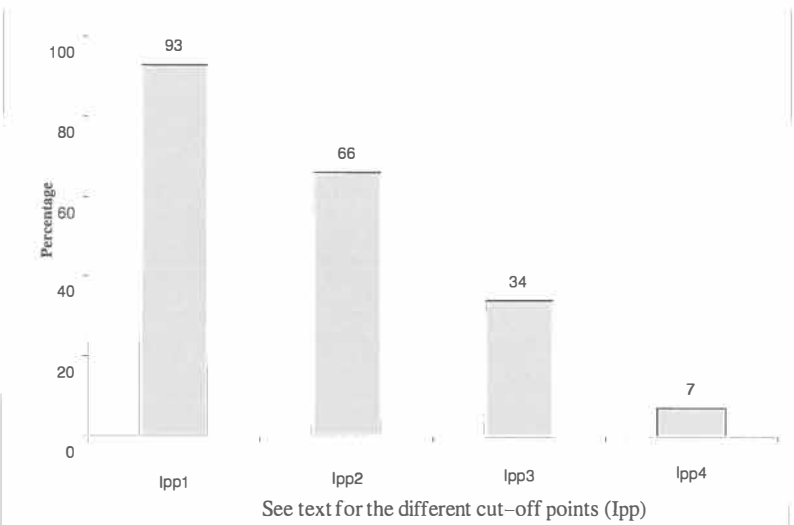

Table 3 Prevalence (frequency) of phantom pain associated with different risk factors for different cut-off points.

	Fpp1	*Fpp2*	*Fpp3*	*Fpp4*	*Fpp5*
Gender					
male	70.9%	51.7%	30.9%	19.0%	8.0%
female	72.0%	54.5%	34.8%	22.7%	10.6%
Amputation level					
proximal or through knee/elbow	**77.1%***	57.0%	33.5%	24.0%	8.9%
distal knee/elbow	**68.5%***	50.0%	31.8%	17.8%	8.7%
Extremity					
upper	**41.1%**	**35.6%**	26.7%	20.0%	10.0%
lower	**78.8%**	**56.6%**	33.9%	20.4%	8.5%
Bilateral					
yes	**94.4%**	63.9%	**47.2%***	13.9%	2.8%
no	**69.7%**	51.6%	**31.3%***	20.8%	9.3%
Amputation reason vascular					
yes	**86.7%**	**70.7%**	**44.1%**	24.5%	9.6%
no	**61.7%**	**40.4%**	**24.5%**	17.3%	8.3%
Stump pain					
yes	**80.9%**	**62.2%**	**38.2%**	**25.6%**	**11.8%**
no	**52.1%**	**31.3%**	**19.6%**	**9.8%**	**3.7%**
Phantom sensations					
yes	**83.0%**	**61.7%**	**38.0%**	**24.3%**	**10.5%**
no	**19.8%**	**10.5%**	**5.8%**	**3.5%**	**1.2%**

Results of Chi-square test. Percentages in bold type: p: significance of chi-square test ≤ 0.05.
* $p \leq 0.049$ but if continuity correction was applied ($p=0.075$) no significant difference was found.
See text for the calculation and definitions of the different cut-off points.

The relationship between impediment due to phantom pain and the different risk factors are listed in tables 4 and 5. The risk factors for impediment of phantom pain changed when different cut-off points were applied. Stump pain and phantom sensation were a significant risk factor for impediment due to phantom pain for two and one cut-off points respectively whereas amputation level (proximal or distal) was a significant risk factor for all cut-off points (table 5).
Because there was a change in risk factors for the different cut-off points and the risk factors for impediment and prevalence were not identical a *post hoc* analysis was performed. A correlation coefficient was calculated between the frequency of phantom pain and the impediment subjects experience (r: – 0.474, p: <0.05).

Table 4 Impediment due to phantom pain in relation to age at time of amputation and time elapsed since amputation for different cut-off points.

Phantom pain	*Yes: mean (SD)*	*No: mean (SD)*	*Mean difference*	P-*value*
Age at time of amputation (years)				
Ipp1	48.0 (22.2)	44.8 (25.1)	–3.3	0.264
Ipp2	49.2 (21.6)	45.2 (23.6)	–4.0	0.057
Ipp3	47.6 (21.3)	48.0 (22.9)	0.4	0.287
Ipp4	46.2 (21.5)	48.0 (22.5)	1.8	0.782
Time elapsed since amputation (years)				
Ipp1	15.7 (15.7)	21.7 (22.2)	6.0	0.217
Ipp2	14.9 (14.7)	18.4 (18.7)	3.6	0.075
Ipp3	16.2 (15.8)	16.1 (16.5)	–9.5	0.651
Ipp4	21.1 (17.5)	15.7 (16.1)	–5.4	0.441

Results of t-test for independent samples. No significant differences were found between the subjects who experienced impediment of phantom pain with respect to age and time elapsed.
See text for the calculation and definitions of the different cut-off points.

Table 5 Percentages of impediment due to phantom pain associated with different risk factors for different cut-off points.

	Ipp1	*Ipp2*	*Ipp3*	*Ipp4*
Gender				
male	93.3%	65.9%	32.5%	6.3%
female	95.0%	69.0%	37.0%	8.0%
Amputation level				
proximal or through knee/elbow	**97.2%**	**74.1%**	**43.4%**	**11.2%**
distal knee/elbow	**90.7%**	**61.1%**	**27.8%**	**3.7%**
Extremity				
upper	97.2%	66.7%	41.7%	5.6%
lower	92.9%	66.4%	33.3%	6.8%
Bilateral				
yes	100.0%	78.9%	44.7%	7.9%
no	92.5%	64.9%	32.9%	6.5%
Amputation reason vascular				
yes	94.8%	70.5%	31.8%	4.6%
no	92.4%	62.7%	36.2%	8.6%
Stump pain				
yes	**95.1%**	**69.1%**	36.8%	7.2%
no	**88.3%**	**57.4%**	27.7%	4.3%
Phantom sensations				
yes	**94.4%**	67.6%	34.6%	7.1%
no	**75.0%**	50.0%	33.3%	0.0%

See text for the calculation and definitions of the different cut-off points. Results of Chi-square test. Percentages in bold type: *p*: significance of chi-square test ≤0.05.

Discussion

The prevalence rate of phantom pain changes considerably when different cut-off points for the frequency of phantom pain are applied. Furthermore, the significance of the relationship between different risk factors and phantom pain changes.

Some studies merely present prevalence of phantom pain without defining their cut-off points for frequency of phantom pain.[12,16,17] Others describe that phantom pain was experienced 'clearly' and 'significantly' by 85% of the respondents.[18] Alternatively they describe that 78% of the respondents 'indicated unambiguously'

the presence of phantom pain.[8] Although the descriptions are extensive, the exact frequencies of experiencing phantom pain behind these cut-off points are not clear. Some studies present a scale of experiencing phantom pain such as 'never, sometimes, often, always' or 'a few times a year, a few times a month, a few times a week, a few times a day, few times per hour, always'.[1,2,5] In those studies phantom pain 'yes' or 'no' are the cut-off points applied. 'No' represents never experiencing phantom pain and 'yes' represents the wide range of experiencing phantom pain from once a year to experiencing phantom pain always.[1,2,5,9,11] It can be debated if this last cut-off point is correctly chosen. Are amputees who experience phantom pain once or twice per year similar to amputees who experience phantom pain always?

From the analyses performed in this study it becomes clear that the choice of cut-off point influences the relationship with the potential risk factors for phantom pain. In table 2 it can be seen that the time elapsed since the amputation is significant for the first three scenarios. Patients with phantom pain had been amputated more recently compared to patients not experiencing phantom pain. This finding suggests that phantom pain diminishes with time, as has been found in previous studies.[3,4,7,8] However, our results show that the choice of cut-off point influences the significance of the relationship. When presence of phantom pain is defined as phantom pain more than a few times a day the relationship is not significant. In all scenarios the relationship between phantom pain and phantom sensations and stump pain was significant. This may indicate that these phenomena are somehow strongly related. For phantom pain and phantom sensation it can be hypothesized that they share the same neurophysiological basis but that there is a difference in intensity. Stump pain on the other hand seems to have another basis such as skin irritation or infections, adherent scars, neuromas, pressure, or bone spurs.[20,21] It is possible that stump pain may trigger a phantom pain mechanism. The significance of other risk factors, extremity, bilateral, or vascular reason depends on the choice of cut-off points.
The association between impediment due to phantom pain and potential risk factors was only significant for three risk factors. One of the risk factors, amputation level, remained significant for all scenarios.
Contrary to our expectations we found a negative correlation between frequency of phantom pain and impediment due to phantom pain. This indicates that if phantom pain is experienced more frequently it does not result in more impediment due to it.

It can be hypothesized that if subjects experience phantom pain frequently, they might get used to this type of pain. If on the other hand subjects experience phantom pain once in a while, they might experience this pain as more impeding because they are not used to it. Another explanation might be that the subjects experience other types of pain that impede them more than phantom pain, for instance back pain.[22,23]

We realise that the different scenarios analysed and presented in this study may be somewhat extreme, but the cut-off points applied by above mentioned authors are similarly extreme. Further this study provides some insight into the differences in prevalence and risk factors found in other studies. A weakness of our study is the amount of non-response on the questions relating to the frequency of phantom pain and the impediment of phantom pain. Possibly age is one of the factors responsible for this non-response because 25% of our population is 74 years or older and these patients are not used to filling out a questionnaire. However, based on the results of this study it is concluded that the choice of cut-off point influences the outcome of phantom pain studies considerably. Therefore, it is recommended that in future studies authors should consider occurrence and impediment of phantom pain or report the choices made in their analysis.

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Chapter 4

Amputation, phantom pain and subjective well-being: a qualitative study

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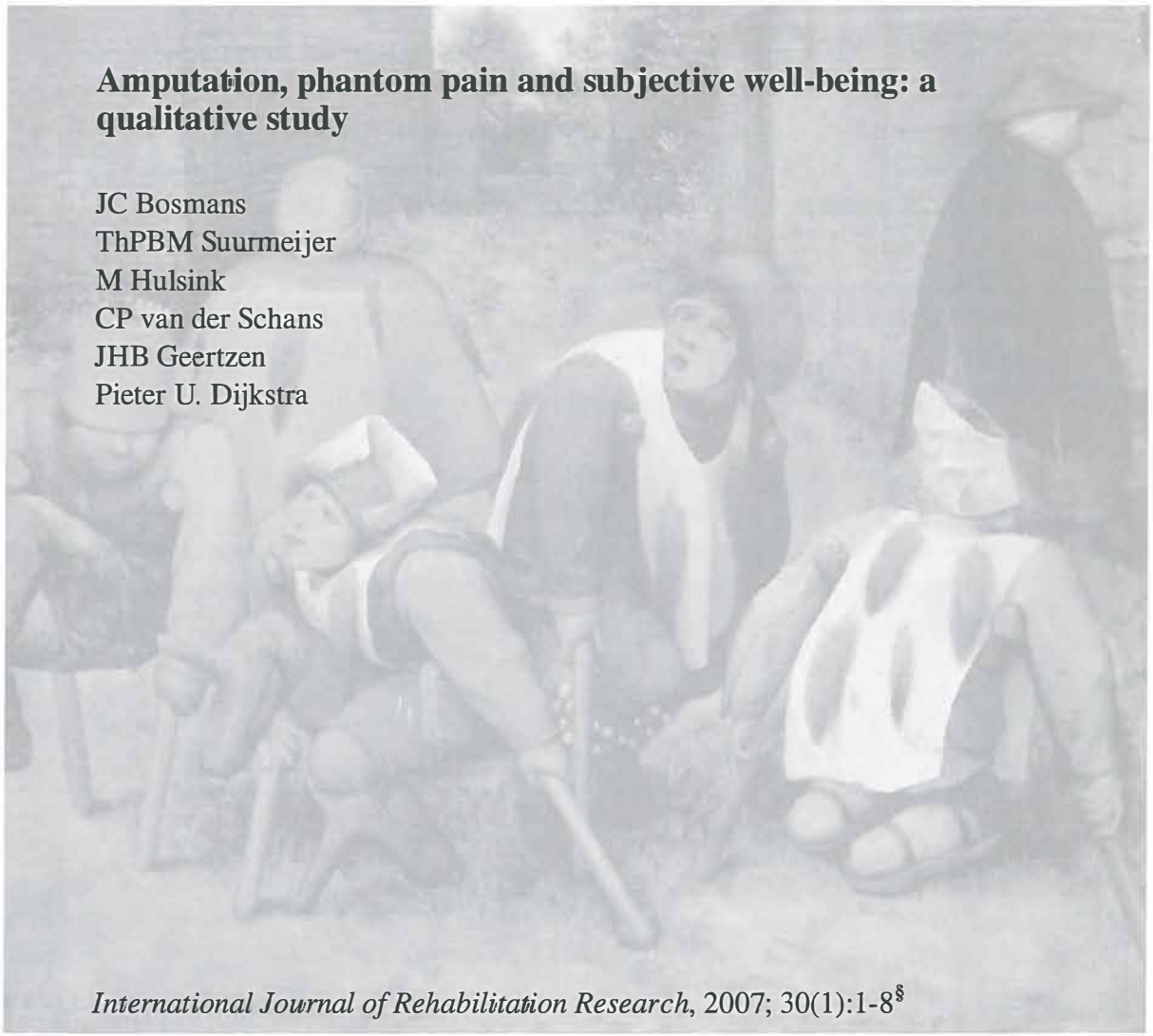

International Journal of Rehabilitation Research, 2007; 30(1):1-8[§]

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Abstract

The purpose of this qualitative study was to explore the impact of an amputation and of phantom pain on the subjective well-being of amputees. Sixteen lower limb amputees were interviewed. A semi-structured interview and two Visual Analogue Scales were used. To interpret the results, a new socio-medical model joining two models, 'The Disablement Process Model', and the 'Social Production Function theory', was used. Questions were asked concerning the factors influencing patients' subjective well-being prior to, at the time of and after an amputation. These factors were patients' medical history, their phantom sensations and phantom pain, their daily activities, the social support they received, and the influence of an amputation and phantom pain on long-term behaviour and on their subjective well-being.

All factors were found to have an influence on the individual's subjective well-being. All these factors, however, seemed to reinforce each other. Therefore, the greatest influence of factors on subjective well-being occurred when more than one factor was involved. Substituting certain activities by others then becomes less and less effective in inducing a sense of subjective well-being.

Introduction

After the amputation of a limb, phantom sensations and phantom pain are common phenomena. Phantom sensations are 'all non-painful sensations in the amputated part of the limb, such as sensations of a certain position of the amputated part of the limb, of something touching, of warmth or cold, or of movements of the amputated part of the limb'. Phantom pain is 'any of the above-mentioned phantom sensations or any other feeling in the amputated part of the limb, which is so intense that it is experienced as pain'.[1]

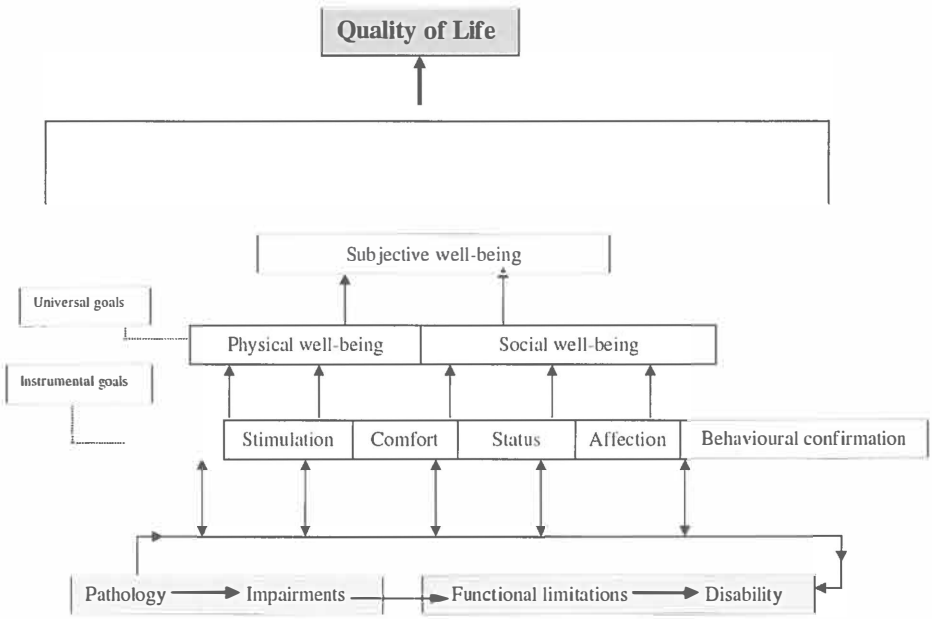
The estimated prevalence of phantom sensations varies from 29% to 78%, while the prevalence of phantom pain varies from 49% to 83%.[2-7] The wide range in reported rates may be attributed to the selection of the population under study, differences in research techniques, and a failure to distinguish between phantom sensations, phantom pain, and stump pain.

An amputation and phantom pain influence the physical and social well-being of everyone affected by them.[8] It may prove to be tremendously difficult to lead a pleasant life again with an amputation and phantom pain; a life in which a sufficient degree of well-being is experienced. In order to achieve this, certain adaptations will be necessary and certain concessions will have to be made. The question is, what are the possibilities and limitations someone encounters in his attempts to experience a better subjective well-being comparable to his well-being before the amputation? Some authors have described the relation between amputation, phantom pain and quality of life[9,10], and used already existing questionnaires[11] or even developed special questionnaires.[9,12] Rybarczyk *et al.* (1992)[10] indicated that the expression of social discomfort by amputees could be seen as a possible indicator for depression. Demet *et al.* (2003)[11] confirmed that physical disability and pain were the most impaired categories of the health-related quality of life (QoL) in amputees.

In this qualitative study we have applied two sociological models in examining the concept of amputation, phantom pain and subjective well-being. Several sociological investigations into subjective well-being have been conducted previously. In social science various conceptual frameworks are used to explain subjective well-being and QoL[13-21]. These models are either sociomedical or sociological models. Subjective well-being and QoL are closely related and sometimes they are regarded as the same[15,20]. For the remainder of this paper only the term 'subjective well-being' will be used.

To substantiate the sociological concept of subjective well-being, two interconnected theoretical models were combined into a new model (figure 1). These two models are the 'Disablement Process Model' (DPM) of Verbrugge and Jette[21] and the 'Social Production Function (SPF) ' theory of Ormel *et al.*[17,18]

Figure 1 The new model.



The concepts in the light grey fields have been taken from the Disablement Process model (DPM), the dark grey field from Spilker (Spilker, 1990) (Baker et al., 1994; Frisch, 2000; Hunt, 1997; Leventhal and Colman, 1997; Ormel et al., 1997, 1999; Pope and Tarlov, 1991; Verbrugge and Jette, 1994) and the others from the Social Production Function (SPF) theory.

The DPM is a sociomedical model, which is built on the conceptual frameworks of Nagi[22] and the WHO.[23] The DPM is used to describe the process from disease to social disability: '(1) how acute and chronic conditions affect functioning in specific body systems, generic physical and mental actions, and activities of daily life, and (2) the personal and environmental factors that speed or slow disablement, namely, risk factors, interventions, and exacerbations'. In this model disability is defined as 'a difficulty doing activities in any domain of life due to a health or physical problem'.[21] Access to resources which facilitate or hamper the

achievement of valued goals is the mechanism underlying the process of disablement. Physical illness, particularly chronic disorders, can be considered one of the main causes of a net loss of (access to) valued resources. These notions are closely related to the second theoretical model, i.e. the 'SPF theory'.

The SPF theory is a sociological model that integrates strengths of relevant psychological theories and economic consumer/household production theories. In the SPF theory subjective well-being is seen as a central goal of human activity and is considered synonymous with psychological well-being. The SPF theory discerns two general, universal goals - physical well-being and social well-being. These two general goals are considered universal goals that all human beings want to attain in order to maximise their experienced subjective well-being. This process depends on their resources and on the way in which they deal with their limitations. The attainment of these general goals, in turn, is explored by the degree to which five first-order instrumental goals, stimulation, comfort, status, affection and behavioural confirmation, are achieved. Stimulation refers to activities that produce arousal, including mental and sensory stimulation, and physical effort. Comfort is a somatic and psychological state based on absence of thirst, hunger, pain, fatigue, fear, and other somatic discomforts. Stimulation, within the pleasant range, and comfort are each related to physical well-being in a positive way. Social well-being results from activities that produce status (refers to a relative ranking to other people), affection (including love, friendship, and emotional support) and behavioural confirmation (the feeling one has 'done right' in the eyes of relevant others, even when direct reinforcement does not occur). The degree to which these five instrumental goals can be achieved depends on the degree to which people have control over or access to, generally stated, intra-, inter-, and extra-personal resources (e.g. occupational and educational facilities and achievements, social skills, social supportive transaction, health status, etcetera). The SPF theory can be used to map changes as a result of radical, life-changing events, e.g. an amputation.[17,18,24] This point of view is also expressed in the WHO QoL group's definition[25] of QoL as 'an individual perception of his/her position in life in the context of the culture and value system in which he/she lives and in relation to his/her goals, expectations, standards, and concerns'.

In short: an amputation and phantom pain may hamper people and may influence their physical, social and psychological functioning, and, consequently, their subjective well-being.

The purpose of this qualitative study was to explore the impact of an amputation and of phantom pain on the subjective well-being of amputees. The influence of physical, social and psychological functioning on the amputee's daily activities and on social roles such as the domestic role, the family role, the occupational role, friendship relations, and leisure activities will be analysed with the help of the model combining the DPM and the SPF theory.

Methods

A convenience sample of 16 patients with a lower-limb amputation (five women and 11 men, age range 39-86 years, average age 66.5 years) was studied. The frequency of age at the time of the study, the reasons for amputation and the level of amputation are shown in table 1. The overall health status of the participants, except for cases of diabetes and vascular disease, was not known.

The recruitment procedure was as follows: six consecutive patients, visiting an orthopaedic workshop (OIM, Haren, the Netherlands) for prosthesis adjustment after they had finished rehabilitation in a nursing home or a rehabilitation centre 1 to 20 years earlier, and 10 consecutive in-patients of a rehabilitation centre (University Medical Centre Groningen, Beatrixoord, Haren, the Netherlands) who had undergone an amputation 1-6 months earlier, were asked by the doctor attending them to participate in the study.

A semi-structured interview (M.H.) was used as the method of research. All interviews were recorded on tape. The interviews were held between April and July 2001. Open questions were used related to the research questions mentioned before. After having been provided with definitions of phantom sensations, phantom pain and stump pain, the subjects were then asked about the following items: (1) their medical history; (2) their phantom sensations and phantom pain; (3) their daily activities; (4) the social support they received; and (5) the influence of the amputation and phantom pain on their long-term behaviour and on their subjective well-being (see Appendix: semi-open interview).

Furthermore, two Visual Analogue Scales (VAS) with scores running from 0 to 10 were used to assess the average intensity of their phantom pain, and their average subjective well-being relative to that of persons in the same age and sex group. A score of 0 on the VAS 'intensity of pain' equals no pain while a score of 10 equals unbearable pain. A score of 0 on the VAS 'subjective well-being' equals a much

lower subjective well-being than that of someone in the same age group, 5 indicates a subjective well-being equal to that of someone in the same age group and 10 means a much higher subjective well-being than that of people in the same age group.

Table 1 Frequency of age at the time of the study, the reason for and the level of amputation (n=16).

Variables	*n*
Age group (years)	
< 41	1
41-50	2
51-60	1
61-70	5
71-80	4
> 81	3
Reason for amputation	
diabetes mellitus	6
vascular diseases	8
trauma	1
infection	1
Amputation	
below knee	13
above knee	3
unilateral	11
bilateral	5

The information gleaned from the interviews was analysed in two phases. Immediately after each interview significant details were written down. In the second phase, the interviews were transcribed verbatim and analysed on the basis of the items in the interview guide. The analyses were then studied in order to see whether they fitted the theoretical model and, if so, how.

Results

Period prior to, at the time of and after amputation

Patient history

At the time of amputation 14 patients already had suffered a longer period of vascular disease or diabetes, which had resulted in vascular surgery more than once. For these patients, it gradually became clear that the leg could not be saved.

> *'I had seen it coming for months that the leg would have to be amputated. I received home care on a daily basis, and the people coming in to help me were also wondering what I was still doing at home, because every day you saw it getting worse. At one point I went to the hospital and told the doctor: "I don't care what happens next, but I am not leaving this hospital!" I was unable to eat or sleep, and then at last the leg was removed.*' (F 1)

Two patients underwent an acute amputation: one man was amputated on the day of his accident and one woman suffered an acute arterial occlusion. They were unable to opt for amputation themselves.

Providing information

Only three patients were informed about possible postoperative pain by the surgeon or the hospital's pain team. Two of these patients found this information not important as it would not lessen their pain. Three others, who received no information whatsoever, had the same opinion. Ten patients indicated they missed having been given adequate preoperative information about pain as it would have given them a better idea of what was going to happen. Everybody had, however, received adequate information about phantom sensations and phantom pain a few days to weeks after the amputation.

> *'There was a pain team at the hospital and they gave me lots of relevant information. I thought that was a good thing, it means you are better aware of what you are going to have to deal with. Some people did not get to hear about phantom pain until they were in the rehab centre and that does make a difference. When you get to hear how it works, that your body is still sending signals to nerves that are*

> *not there any more, you deal with it differently than when you don't have a clue about what's going on. I don't know whether one experiences the pain differently, but I endure it more stoically because I know what to expect.*' (M 2)

Phantom sensations

Fourteen patients had the sensation of still having their leg. Some patients even forgot they had lost their leg, falling as a result. This sensation faded away some weeks after amputation. Yet one woman still had this sensation two years after surgery.

Other phantom sensations were itching of the heel and calf, below the amputated part, a tingling sensation, and numbness.

Phantom pain

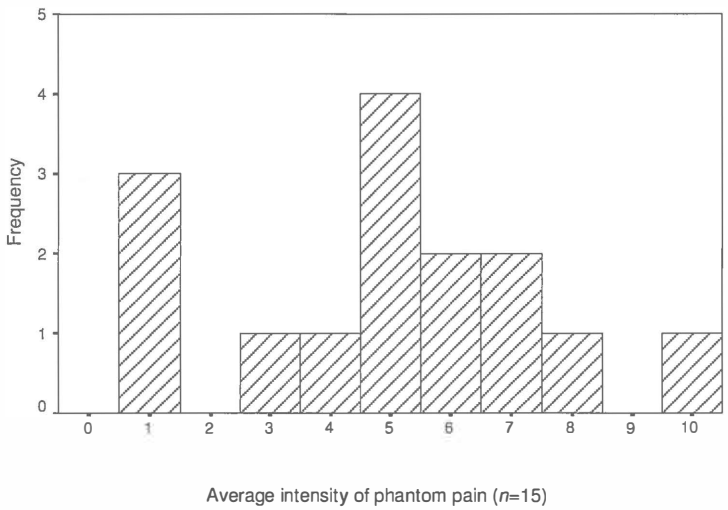
Thirteen patients experienced phantom pain, but there was a great variation in intensity. Four patients occasionally experienced unbearable phantom pain, describing the pain as shocking, throbbing, a sensation of numbness, tingling, or aches of previous wounds on the amputated limb. One man related that the phantom pain could last half an hour, with the remaining leg stump convulsing and with him being unable to restrain it.

Three patients experienced their phantom pain as being not so bad as to be called unbearable. They still experienced annoying, painful sensations at times. They often used different terms to describe the pain, like numb, nagging, stinging, prickling, and stabbing.

> *'To tell you the truth, I hardly experience any phantom pain at all. The only thing I feel is an occasional slight shooting pain in my toes, and sometimes I experience a slight tingling sensation, but it is hardly worth mentioning.'* (M 5)

Figure 2 shows the average of intensity of phantom pain as experienced by the patients. Various patients mentioned having unbearable pain, but at the moment of completing the VAS they did not rate their pain as unbearable. According to the patients their pain was variable. One patient did not fill in the score, because he considered pain to be immeasurable. At one time he had suffered such unbearable surgical pains that, in comparison, everything else hardly counted as pain.

Figure 2 The average intensity of phantom pain experienced by the patients (n=15).



One patient did not fill in the score, because he considered the pain to be immeasurable.

All patients suffering pain tried to ease it in their own way. A number of patients used sedatives (temporarily), muscle relaxants, antidepressants, or sometimes they had a drink. Rubbing the painful spot of their phantom leg on their healthy leg was mentioned, as was stamping a foot, or kneading the stump. Three-quarters of the patients indicated that doing an activity distracted their attention and decreased the pain. Many distracting activities were mentioned, such as fishing, reading, watching TV and shopping. One quarter did not benefit from doing an activity. These patients experienced unbearable pain sometimes.
They tried to distract themselves but that did not work. Therefore they immediately stopped doing what they were doing and then lay down as quietly as possible. Phantom pain obviously influenced their day schedule. Two men experienced their strongest pain while driving their car, whereas one man coped with his phantom pain by driving his car. For one patient, doffing his prosthesis did not help to decrease his phantom pain, but some others suffered less pain after doffing the prosthesis.

> *'Phantom pain is a lacerating pain that one really cannot stand. As a result, I cannot hold my leg still. The pain always comes during the night, so I don't sleep at all. It is only when I don the sheath of my prosthesis that the pain gets a bit more bearable.'* (M 6)

> *'Whenever I experience phantom pain, there is nothing that helps. I go and lie down on the couch as quietly as possible and doff my prosthetic leg. Not that that really helps, but most of the time I do it anyway.'* (M 7)

The influence of an amputation and of phantom pain on long-term behaviour

After the rehabilitation treatment social life became important again for the patients.

> *A man who was staying at a rehabilitation centre stated: 'Because of the amputation, I plan my day in a completely different manner, starting with the way I spend the morning. I can manage everything on my own, I don't need any help at all, but it all takes al lot longer. I wash myself at the wash basin, I don't take a shower anymore, I don my prosthesis and then I am ready and sit there twiddling my thumbs. That's the way it is around here, but I expect it to be the same when I am back home. I cannot go cycling or go for a walk any longer, things I used to do all the time. I used to go out awfully often. Sometimes I took the car, but I won't be able to learn to drive again. I've got an electric car, but it's no good for shopping, for you can't take anything along. So now I just sit around and read a lot.'* (M 8)

Social disability may be experienced in a number of behavioural domains, affecting the domestic role, the family role, the occupational role, relations with friends, and leisure activities.

Changes in the domestic role

Two of our patients moved to a home for the elderly. One of them liked this because it meant she was going to live nearer her son, which was very important to her. The move was an improvement of her living situation at the time. Others had their house adapted (bedroom downstairs and supports in the shower and the toilet). Patients who were staying in their own house were aided by their partner or a home help most of the time. Few problems with the household chores were experienced or expected.

> *'My future lies in a nursing home, for I cannot be at home on my own and can no longer cook my own meals, whereas I used to do so every day. I am afraid that the people around me will see me in a different light, for I am no longer the man I used to be when I was still well.'* (M 9)

Changes in the family role

According to all patients, the relationship with their partner had become closer as a result of the amputation, because the partners were more often in each other's company or because the partners were more dependent on each other. Partners took on responsibility for the amputee, expressing this by caring more and showing a greater concern. Many patients liked this greater care, but two found the concern too much to handle. Nobody thought the relationship had deteriorated. Children were also more caring than before. They watched their parent, taking care that he or she did not fall or did too much, so as to prevent their phantom pain later that day. Most children visited their parent more often shortly after the amputation and during rehabilitation, but later on these visits ceased.

> *'I cannot drive a car by myself any longer, also because of my poor eyesight, but my wife takes me everywhere and does so quite cheerfully. We have a lot of fun together now.'* (M10)

> *'My wife has a really hard time coping with the fact that I have only one leg. She has always supported me, but then I tell her she shouldn't help me all the time because I want to and I have to do it all myself. But she still wants to help me in some way.'* (M 11)

Changes in the occupational role

Seven people were under 65 (the age of retirement in the Netherlands) at the time of surgery. Three of them were able to continue to do the same work but at a slower pace. One man undertook other work within the same company. All these patients were satisfied with the way they were able to do their work in their new situation. One man had to look for a new job, because he could not go on in his old job physically. After staying at home for ten years, he was now working at a sheltered workshop and he was glad to be at work, having other things to think about and feeling useful again. A woman, aged forty-one, wanted to work but

could not find a job that was adapted to her needs, nobody took her on. Not finding a job made her feel inferior to people who did have a job.

> *'They don't need me. I did apply for a job, but I cannot stand upright for any length of time, and I have to walk a lot. I cannot do any work for which I have to stretch. It has to be a job that fits me, but I don't have much of an education, two years of domestic science only. That is frustrating.'* (F 2)

Changes in relations with friends

The amputees handled the situation with their friends in different ways. For most people the phantom pain did not influence their friendships.

> *One man stated: 'It is not in my head, but it is all below my knee. And when they ask how I am, then I say: "I'm okay and how are you?" End of conversation.'* (M 12)

Another man cancelled his engagements whenever he felt the phantom pain coming on. Friends found that difficult sometimes, because they felt they could not count on him. The man himself did not like it, but at the moment of suffering this phantom pain he could not do anything at all. In some cases, the phantom pain influenced the amputee's friendly contacts. One man was shunned by a number of his football friends. His feelings were hurt and therefore, he chose to ignore them.

Changes in leisure activities

The skills most missed were walking, biking and driving a car. Some patients had an electric car. A number of patients drove a (half) automatic car. Some amputees expected to be able to drive again in an adapted car. Those who did not drive themselves had looked for and found other solutions to this problem.

Many patients had to give up their hobbies as a consequence of the amputation, and had tried to find new hobbies. One person had learned to draw; another went out and about with his electrical car instead of going for a walk. One man had had no time for hobbies earlier, because he always worked so hard and now he did not know what to do after his amputation. Another man used to do many cryptograms and play bridge, but as a consequence of a large number of surgeries his memory

had been affected. Most patients found it difficult to spend the day in a meaningful manner.

> *'I used to like volleyball a lot. The other day, watching a volleyball tournament, I felt like shit for a moment. You want to do a jump service, but that's out of the question, of course. That feeling only lasts a short while, for a bit later I remember that there are also people having a prosthesis who still play volleyball. Or else I can learn to play ground volleyball. Sport as a hobby is not going to be what it was before, but I'll manage. I'll just take up another sport.'* (M2)

The influence of an amputation and of phantom pain on subjective well-being

Some time after the amputation the patients had to resume normal life again. Not everyone, however, had or saw the same possibilities, so the experienced subjective well-being varied. Patients were asked to fill in a VAS to assess subjective well-being relative to that of persons in the same age group.

> *'Actually, this illness has enhanced my quality of life. There's more to life than just work, a lease car and going on holiday. Also, I don't feel disabled or anything. I feel, like, I am going to go on with my life and I am going to do lots of fun things and so on. Also, I've come to live my life with greater awareness: that happens automatically when you are faced with a situation in which you don't have a choice. A kind of acceptance. It's not that I say WOW, I've got a prosthesis, but for the rest?'* (M 11)

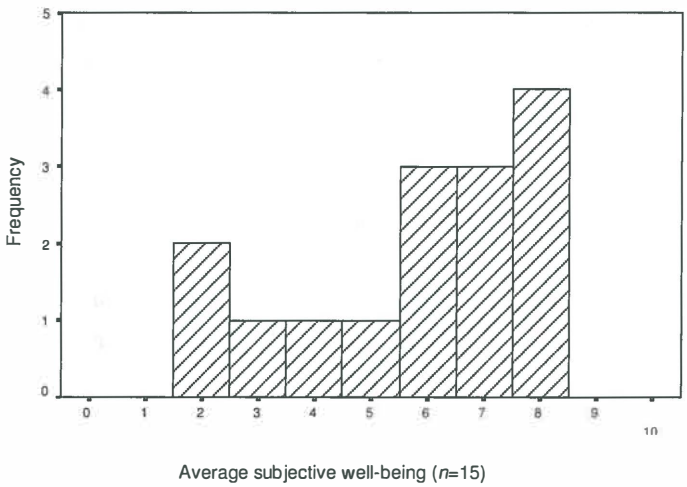
> *'I feel fine right now. At first, I lost over 20 pounds, but now I'm fine. I feel confident that things will turn out well. In a little while there will be a place for me in the nursing home and then I'll be living close to my son again and everything will be fine then.'* (F 5)

> *'When I hear about people in my age group, then I am a lot happier, for I live rather modestly. Others can afford lots and lots more, so they have lots and lots more on their mind. And I haven't.'* (M 8)

Figure 3 shows how people (n=15) experienced their subjective well-being as compared to that of other persons in the same age and sex group. One patient

experienced the same subjective well-being as compared to that of other persons in the same age group. Two-thirds (n=10) experienced a little higher or much higher subjective well-being and 27% (n=4) a little lower or much lower subjective well-being.

Figure 3 The average subjective well-being as compared to that of other persons in the same age and sex group.



A score of 0 on the VAS 'subjective well-being' equals a much lower subjective well-being than that of someone in the same age and sex group; 10 indicates a much higher subjective well-being than that of people in the same age and sex group (n=15). The score was not available for one person.

One man, who was still able to work, experienced his life as being more valuable after his surgery and expected his subjective well-being to increase over the next year, after having finished the process of rehabilitation. The average subjective well-being of amputees still undergoing rehabilitation, was similar to that of other people in the same age group. The experienced subjective well-being of those who had finished treatment was slightly higher than their peers. Patients often mentioned their life having become different, not less worthwhile. One man estimating his subjective well-being at 4, stated that this number was much lower when he was experiencing phantom pain. He did not include phantom pain in defining his current subjective well-being, nor did several others. In some cases, respondents, in spite of suffering severe phantom pain, rated their subjective well-being as high, whereas respondents with hardly any pain rated their subjective well-being as low.

Discussion

To interpret the results, a relation with the used theoretical research model (figure 1) has been established. In this model the pathology is diabetes or a vascular disease resulting in a lower limb amputation. Each respondent underwent an amputation and suffered from phantom sensations and phantom pain, but for each person the influences of phantom sensations and phantom pain on subjective well-being proved to be different. Individuals aim for a subjective sense of well-being by means of instrumental goals 'stimulation, comfort, status, affection and behavioural confirmation', making use of the available resources and dealing with the limitations resulting from their personal situation in their own way.

Period prior to, at the time of and after amputation

The instrumental goal comfort was particularly influenced by changes in the patients' health and the physical discomfort after an amputation with its concomitant phantom pain. On the other hand, the amputation sometimes removed the physical discomfort (pain) existing preoperatively. The experienced effect of stimulation was influenced by the great, physical effort of recovering from the amputation. Stimulation up to a certain level often increased the patient's well-being, but continued strong stimulation was experienced as unpleasant[26]. As a result of having no specific tasks and of having lost special skills, the patients' status and behavioural confirmation were negatively influenced as well. At the moment of the interview, however, this influence was not very large, because physical well-being was found to be more important directly after the amputation. The influence of affection was often found to be strong; family and friends often visited the patient, and relationships became closer. But relationships sometimes deteriorated because people did not visit anymore. The greatest effects of affection were, however, visible in the long run.

Summarising, it is mainly the instrumental goals related to physical well-being (stimulation and comfort) that play a positive role in achieving subjective well-being. Instrumental goals related to social well-being (status, affection and behavioural confirmation) sometimes play a positive, sometimes a negative role in achieving subjective well-being.

The influence of an amputation and of phantom pain on long-term behaviour

The long-term consequences of an amputation and its concomitant phantom pain on a patient's well-being are different from the short-term consequences. In the long run it should be clear to the patient what the permanent consequences of the amputation are and he should gain an insight into its social consequences.

The influence of comfort and stimulation on a patient's physical well-being depends on the level of recovery (e.g. the possibility of walking again/wheelchair dependency). More pain and a less successful recovery decrease a patient's physical and personal well-being. The influence of amputation and phantom pain on social well-being is different for each patient.

From the interviews it became clear that phantom pain had different consequences for the different patients. Some lost touch with relatives, some were not able to work and some had to cancel appointments. Phantom pain had a negative effect on the subjective well-being of some patients because it diminished their comfort, forcing them to suspend certain physical activities and causing severe psychological stress. Phantom pain influenced the social well-being of some of the patients by hampering them in achieving status, affection and behavioural confirmation. When phantom pain was unbearable patients tried to find diverse solutions to lessen it. Being unable to influence the pain caused frustration in these patients.

It was found that a paid job can play a role in the patient's achievement of status and behavioural confirmation, depending on the kind of occupational life he or she led before the amputation. If there were possibilities of adaptation, the negative influence on the person's well-being was less, but if other employment had to be looked for, the negative influence was strong.[27] One loses unique skills and colleagues, which may also result in a loss of affection. Amputation may make a disorder visible, so the person does not have to work any more. In this way the amputation had a positive influence on his well-being, which was not expected before.

The existence of a partner and friends influences affection, which is one of the main instrumental goals in achieving well-being. After amputation there is a need to talk about this major life change with the partner. To diminish the consequences of the amputation a partner may also help with practical things. Domestic tasks were not found to have a great influence on the patient's subjective well-being.

Many elderly patients had already left a part of their household chores to others, so they did not lose status or behavioural confirmation.

The influence of an amputation and of phantom pain on subjective well-being

An important determinant of subjective well-being after an amputation appeared to be independence. The ability to perform daily activities such as going to the toilet, (un)dressing and washing decreased comfort so much after an amputation, that these skills were relearned as soon as possible. The skills most missed were walking, biking and driving a car. These skills were very influential in inducing a sense of well-being. Dependency hampered patients in carrying out their daily activities - shopping, working, pursuing hobbies, doing sports and visiting family and friends - and in this way hampered them in achieving status, affection and behavioural confirmation.

A patient's future prospects formed another determinant influencing his well-being. If the expectation is that the prospects will not be better after rehabilitation treatment, then that will have a negative influence on well-being. But if the future is expected to bring improvement, then the patient has something to aim for.

From the interviews it appeared that whenever a patient was able to substitute his job by another job or activity, the final influence of an amputation on his well-being was not as extensive as in the cases where there was no substitution. But, due to the negative influence of intense phantom pain, it was found to be increasingly difficult to find substitute activities. Having meaningful roles or activities, such as leisure activities, occupational activities or the support of family and friends, were expected to be important to the patients' satisfaction in life, as has been confirmed in other studies[28, 29]. Nearly all patients stated that doing activities distracted their attention. The words they used, however, were so similar that after a number of interviews we suspected that these phrases came from a doctor or a therapist. It was not clear if the patients really found it useful to do activities or not.

Summarising, in the long run after an amputation and its sometimes concomitant phantom pain instrumental goals related to physical (stimulation and comfort) and social well-being (status, affection and behavioural confirmation) were seen to play a role in achieving well-being in some patients. In case of unbearable phantom pain it influenced the patients' physical and social well-being. It became clear that being physically independent, having a job, a partner and friends, and having future prospects caused the influence of an amputation to be less far-reaching than in cases where there was no substitution of meaningful roles or activities.

Reflection on research methodology

In this study a semi-structured interview and two VAS scales were used to measure the level of phantom pain and the subjective well-being, compared to that of people in the same age and sex group. The disadvantage of a semi-structured or open interview is the possibility of being subjective. The way in which questions are asked and/or the attitude of the interviewer may influence the interview.

The level of pain as measured on the VAS probably paints too rosy a picture. First the patients did not indicate their utmost pain but an average pain. Second, socially desirable answers may play a role. Patients sometimes stated to suffer unbearable pain; however, filling in the VAS, they indicated a pain that was a lot less than unbearable. Maybe people did not like to complain, which, in turn, may be valued as 'behavioural confirmation' enhancing feelings of well-being.

In our study the subjective well-being was only measured once, and only compared to the subjective well-being of people in the same age and sex group. Our patients were not asked to rate their own well-being. So it is not possible to compare our patients' subjective well-being with the subjective well-being as given by Cummins[30,31] who stated that the life-satisfaction gold standard could be considered to be 75.0 (sd ± 2.5%) on a scale of 0-100.

An important advantage of a qualitative study is the possibility to gain a deeper understanding of social aspects, which were not previously known. The way an amputation and phantom pain influence patients' subjective well-being can only be clearly surveyed when it is clear which factors play a role in this process. A disadvantage of a qualitative study is that the possibility to generalise from such data is limited. Furthermore, we interviewed a limited number of patients (n=16).

We did not concern ourselves with the number of patients suffering from stump pain; since studies on phantom pain[5,6,32] have shown that patients were afraid to report phantom pain for fear of being considered insane or of jeopardizing treatment of their stump, we only wanted to explore phantom pain. This may be regarded as a major limitation of this study. In a previous study it was found that 48.1% of a group of 104 lower limb amputees complained about stump pain[33] and that may have an impact on patients' well-being.

In subsequent research a clearer difference between the average pain and the worst pain and between phantom pain and stump pain should be made, the patients' own well-being should also be assessed, and there should be different times of measuring.

Conclusions

The purpose of this qualitative study was to explore the impact of an amputation and of phantom pain on someone's subjective well-being. The direct influence of phantom pain on the subjective well-being appeared to be small for the majority of the patients. Unbearable phantom pain was, however, found to have quite a large influence on the patients' subjective well-being. The influence on well-being was less when patients were physically independent, had a job, had a partner and friends, and had prospects compared to when patients had no substitution of meaningful roles or activities.

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Appendix: semi-open interview

General

1. What is your date of birth?
2. When did your amputation take place?
3. What was the reason for the amputation?
4. How was your physical condition prior to the amputation, were you also in pain at the time?
5. Were you informed that you might suffer from phantom pain after amputation?

Focal point: phantom pain

1. What are your experiences with phantom pain?
2. How are you coping with the pain?
3. Is there a clear difference to be made between phantom pain and phantom sensations? How?
4. How do you feel about phantom pain?
5. How much pain do you suffer?
6. Do you suffer from fatigue a lot? Is this because of the pain?
7. Do you suffer more or less pain when you are tired?
8. Do you suffer more or less pain when you are occupied?
9. Are there occasions when the phantom pain hampers you in making the choice you would want to make?
10. Are there occasions when you refrain from doing something because of the phantom pain?
11. Whenever you suffer severe phantom pain, do you get on with the things you set out to do?
12. Does suffering more phantom pain also mean it has a bigger influence on your life?
13. Are you able to influence the phantom pain, can you bring on or lessen the pain at will?
14. Is your phantom pain predictable?

Focal point: the situation at home

1. What things are you unable to do any longer after the amputation and what do you miss most?
2. What are you unable to do at the moment because you suffer from phantom pain?
3. What are the consequences for your daily activities?
4. Are there any daily activities which you stopped doing, or which you do with some adaptation or other?
5. What are the consequences for your activities with regard to the household chores?
6. Are there any household chores you have stopped doing, or which you do in a different manner?
7. Have you had to sacrifice (part of) your independence?
8. Do you plan your day differently now?

Focal point: the situation in the social environment

1. Have there been any practical or psychological changes in the relationship with your partner, because of the amputation?
2. Do you do other things together now?
3. What are your feelings on that?
4. When things are going bad in your relationship, do you then suffer more phantom pain?
5. Do things get worse in your relationship when you are in a lot of pain?
6. Has the amputation or the phantom pain had an influence on your job?
7. Have you had to get another job, or did you have to have some adaptations within your job? (on the work floor?)
8. What are your feelings on that?
9. Have there been any changes in the friendships you had, after the amputation or because of your phantom pain?
10. Are your feelings on friendship any different now? Do your friends feel or behave differently towards you?
11. Are there any people who found it difficult to cope with the situation?
12. Did you yourself find it difficult to cope with the stigma of an amputation?
13. Do you have people who can support you or help you?
14. Do you suffer more phantom pain when things are not going smoothly in a friendship?

15. Do you or did you engage in sports?
16. Do you or did you have any hobbies?
17. Has the amputation or the phantom pain forced you to give up any sports or hobbies?
18. What are your leisure activities nowadays?
19. Do these leisure activities have an influence on the phantom pain, or vice versa?
20. Do you cancel appointments more often than before?

Focal point: effects on the subjective well-being

1. Are there things which you used to think very important and which now you do not find important at all, or vice versa?
2. Is this because of the amputation, because of the phantom pain, or are there any other causes?
3. When you are feeling better, do you then cope with the pain better as well?
4. Does the phantom pain have an influence on your well-being? If so, in what way?
5. Did your job, your partner, your friends or daily activities have an influence on the phantom pain or on your feeling of well-being?

Chapter 5

Determinants of phantom limb pain: a 3½-year prospective study

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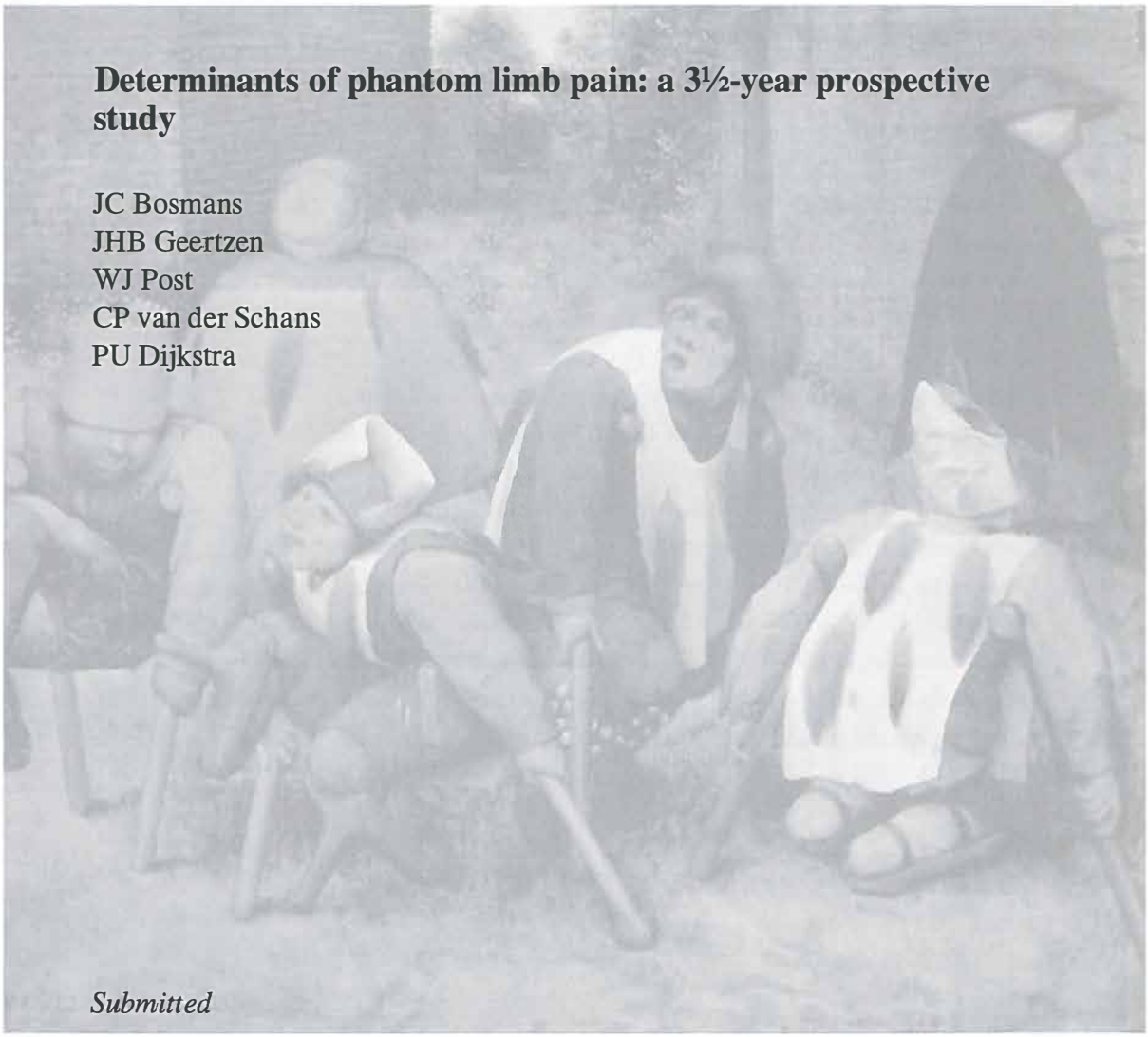


Submitted

Abstract

Objective: To analyse the prevalence of phantom limb pain (PLP) over time and the determinants of PLP in a prospective cohort of limb amputees.
Design: A multicentre longitudinal study.
Patients: 134 patients scheduled for amputation were included.
Methods: Patients filled in questionnaires before amputation, and postal questionnaires 6 months, 1½ years, and 2½ years to a maximum of 3½ years after amputation. Preoperative assessment included patients' characteristics, date, side and level of, and reason for amputation. The follow-up questionnaires assessed the frequencies of the experienced PLP, prosthetic use and walking distance.
Results: Pre- and postoperative questionnaires were available filled in by 85 amputees (33 females and 52 males). The percentage of lower-limb amputees with PLP was the lowest at 6 months and 1½ years after amputation. In general, more women than men experienced PLP. One and a half years and 2½ years after amputation the highest percentages of the lower-limb amputees used their prosthesis ≥ 4h/day (66% and 68%, respectively), after that time this percentage decreased to 56%. The results of the 2-level logistic regression analysis to predict PLP show that PLP was less frequently present in men (β=-2.09), in lower-limb amputees (β=-1.95) and that it decreased in due course (β=-0.65, per year).
Conclusion: Protective determinants for PLP are being male, having a lower-limb amputation and the time elapsed since amputation.

Introduction

Phantom limb pain (PLP) is a common problem after a limb amputation. The prevalence rate of PLP for all limb amputees ranges considerably (41 to 85%).[1-5] This wide range may be ascribed to differences in study populations, in the place of amputation (upper or lower limb), in the research design (prospective, retrospective or cross-sectional) and in the method of assessment (interview or questionnaire), to a lack of a clear definition of PLP, or it may be ascribed to differences in cut-off points for phantom pain.[1;4;6-9] Generally, it is assumed that PLP decreases slightly over time. However, the prevalence rate remains more or less constant, but the duration and frequencies of PLP attacks decrease.[4;5;7;10-13] Numerous factors have been associated with the development of PLP, including age, reason for amputation, pain prior to amputation, time elapsed since amputation, presence of phantom limb sensations or stump pain, dominance of the amputated upper limb and prosthetic use.[1;3;4;8;10;12;14]

Especially from a rehabilitation perspective, the cause-effect relationship between PLP and prosthetic use is important. With less frequent and less intense PLP and more prosthetic use amputees will regain as much independence in daily activities and mobility as possible and hence, will achieve a more successful functional outcome after amputation. The explanation of the association between PLP and prosthetic use, however, remains controversial and it is still unclear whether the experiencing of PLP is influenced by prosthetic use or vice versa.

The cause-effect relationship between the aforementioned risk factors and PLP remains unclear. Much of what is known up till now has been obtained from cross-sectional studies in which subjects were studied for several years after their amputation. Until now only few longitudinal studies have been published in which the different risk factors for developing PLP have been studied. Those studies, however, had relatively small population samples and the long-term follow-up seldom exceeded 1 year.[10;12;15-18]

The aim of this study was to analyse the prevalence of PLP over time and the determinants of PLP, viz. age, sex, place of amputation (upper or lower limb), reason for amputation, level of amputation, time elapsed since amputation, prosthetic use and the ability to walk a certain distance (abbreviation 'walking distance'), in a prospective cohort of limb amputees.

Methods

Study set-up

Between the first of November 2003 and the first of May 2007, patients scheduled for a limb amputation because of either a peripheral vascular disease (PVD) with or without diabetes mellitus (DM), an ulcer, an infection, cancer, a trauma or a complex regional pain syndrome (CRPS I) were asked to participate in this prospective multicentre study on phantom limb pain (PLP). One university hospital and five general hospitals in the Northern Netherlands participated in the study. The medical staff of the participating hospitals informed the primary investigator [JB] about potential participants. After being informed about the study by the medical staff and after having agreed to participate in the study, the patients were approached by the primary investigator and the study goals and study design were explained to them. Inclusion criteria were (1) age $\geq$ 18 years, (2) ability to read and write Dutch, and (3) an amputation level through the metacarpal or metatarsal phalangeal joints or more proximal. Patients were excluded if (1) they had had a previous ipsilateral amputation, (2) they showed signs of clinical dementia to such an extent that they could not be expected to fill in the questionnaires reliably, (3) they were too ill to be able to fill in the questionnaires or (4) the time interval between their amputation and inclusion exceeded five days. After patients gave their written informed consent, they filled in questionnaires before or within five days (T_0) after amputation. Patients agreed to fill in follow-up questionnaires at the following intervals: 6 months (T_1), 1½ years (T_2), 2½ years (T_3) to a maximum of 3½ years (T_4) after amputation. To motivate amputees to continue participation during the follow-up, they were contacted by telephone [JB] before being sent the follow-up questionnaires. If amputees were still willing to participate, the questionnaires were posted to them, with a post-free self-addressed envelope. Amputees were asked to fill in the questionnaires regardless of the presence or absence of PLP, and regardless of whether they had a prosthesis or of their ability to walk.

Questionnaires

Patients were asked to complete either the 'Groningen Questionnaire Problems after Leg Amputation (GQPLA)'[4;9;19] or, in case of an upper-limb amputation, the 'Groningen Questionnaire Problems after Arm Amputation (GQPAA)'.[3] To distinguish phantom pain from other phenomena, phantom limb pain (PLP) was

defined as any painful sensation perceived in the missing part of the limb after amputation.20 Phantom limb sensations were defined as any non-painful sensation in the missing part of the limb, such as sensations of the missing part of the limb being in a certain position, of something touching, of warmth or cold, or of movements of the missing part of the limb. Stump pain was defined as any painful sensation in the stump, the remaining part of the limb.[3]

Preoperative variables

The preoperative assessment included patients' characteristics (date of birth, sex) and date, side and level of, and reason for amputation.

Postoperative variables

The follow-up GQPLA assessed the frequencies of the experienced phantom limb pain (always, a few times an hour, a few times a day, a few times a week, a few times a month, a few times a year, never), having a prosthesis (yes/no), prosthetic use (time of use: ≥8 hours daily, 4 to 8 hours daily, <4 hours daily, not daily but .. days a week, never) and walking distance with the prosthesis (≥1 km, 500 m to <1 km, 100 to <500 m, <100 m). The GQAA asked the same questions, walking distance excepted, with a few added questions about the type of prosthesis (cosmetic, mechanical, myoelectrical).

The last follow-up date was the 30th of April 2008, meaning that the duration of the follow-up was not the same for all patients.

The study protocol was approved by the medical ethical committees of all hospitals participating.

Data entry

Before entering the data from the questionnaires, the medical information provided by patients was verified in the medical records and, if necessary, corrected.

The reason for amputation was categorized into PVD (peripheral vascular disease with or without DM, an ulcer, an infection), cancer or trauma (trauma and/or CRPS I). Trauma and CRPS I were grouped in one category for two reasons: because in most cases CRPS was induced by trauma and to generate a group of patients with sufficient number of amputations. Lower-limb amputations were categorized into distal (transtibial, ankle or foot), knee disarticulation (KD) or proximal (pelvis, hip or transfemoral). Upper-limb amputations were categorized into distal (forearm or wrist) or proximal (forequarter, shoulder or upper arm); no elbow disarticulations were performed.

In case of a second amputation of the same extremity during the study period, the level of the last amputation was used for statistical analyses. In case of a bilateral lower-limb amputation during the study period, the side of the first amputation was entered in the database. If the first amputation of the bilateral amputation was performed before the study was started, then the latest amputation was entered in the database. If an amputee died or dropped out during the follow-up, this was recorded.

The answers to the questions were entered in the database and checked for correct data entry. Data were processed anonymously. The data were categorized as follows:

- Phantom limb pain present: PLP a few times a day or more frequently against a few times a week or less frequently. We assumed that, when patients were asked to fill in the questionnaire, they remembered daily PLP better than those who suffered from PLP less frequently. So it was decided to choose the aforementioned cut-off points for PLP.[9]
- Prosthetic use: prosthetic use ≥4 hours per day against prosthetic use < 4 hours per day. This cut-off point was chosen arbitrarily.
- Walking distance (in case of a lower-limb amputation): walking distance ≥500 m against walking distance <500 m. We assumed that a walking distance of at least 500 m is needed to function independently indoors as well as outdoors (ability to walk from the parked car to a shop, to visit shops in the neighbourhood, recreational possibilities).[19]

Statistics

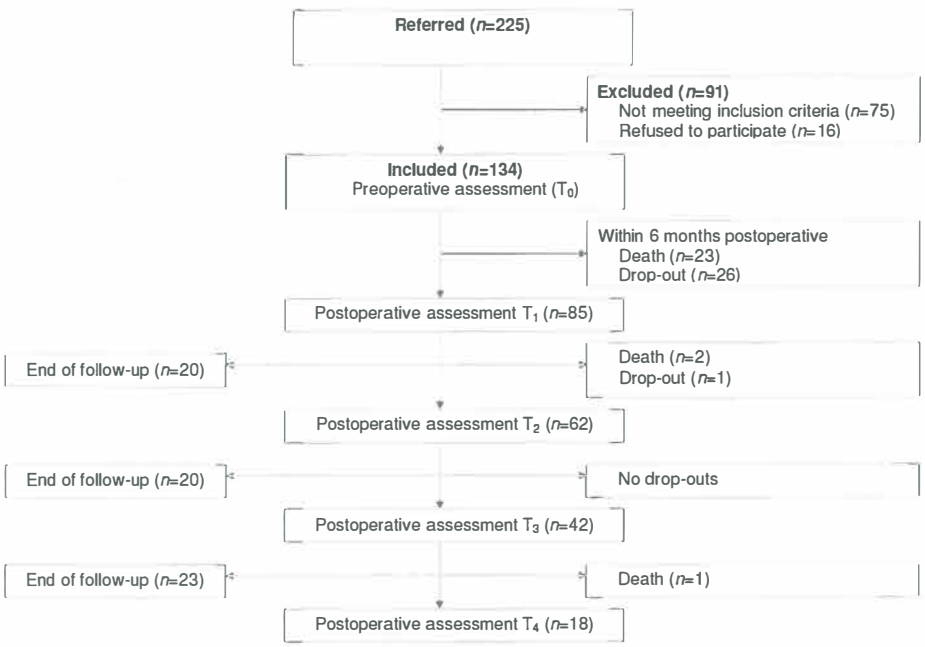
Statistical analyses were performed using SPSS 16.0 for Windows. Differences in characteristics between included patients on the one hand and drop-out patients and excluded patients on the other were analysed using t-tests for independent samples and χ2-tests as appropriate. A 2-level logistic regression was performed in ML Win 2.02. Patients were the highest level, and time was the lowest level. The dependent factor was presence of PLP and as possible predictors were entered age, sex, upper- or lower-limb amputation, reason for amputation, level of amputation, prosthetic use and walking distance. Categorical variables were entered as dummy variables. Random and fixed effects were taken into consideration. Possible interactions were explored. Independent variables remained in the regression equation when the β's were significant.

Data regarding amputees who filled in a pre-amputation questionnaire, but who died or dropped out in the first 6 months after amputation, were excluded from the analyses, because no data on PLP, prosthetic use and/or walking distance were available.

Results

In total, 225 patients scheduled for a limb amputation were referred to this study. One hundred and thirty-four patients (120 lower-limb and 14 upper-limb amputations) fulfilled the inclusion criteria and filled in the first questionnaire (preoperative assessment). Ninety-one referred patients were excluded because they did not meet the inclusion criteria (n=75) or did not want to participate (n=16).

Figure 1 Flow diagram of patients referred.



Six months after amputation 37% (49 out of 134) amputees were lost to the follow-up because of dying (n=23) or dropping out (n=26). Hence, 85 amputees filled in two or more questionnaires (a preoperative assessment and at least one

postoperative assessment), of whom 23 patients filled in two questionnaires (a preoperative assessment and one postoperative assessment), 20 patients three questionnaires (a preoperative assessment and two postoperative assessments), 24 patients four questionnaires (a preoperative assessment and three postoperative assessments), and 18 patients five questionnaires (a preoperative assessment and four postoperative assessments) (figure 1), resulting in a total of 292 questionnaires, which were available for analysis.

Table 1 Characteristics of all limb patients referred to the study.

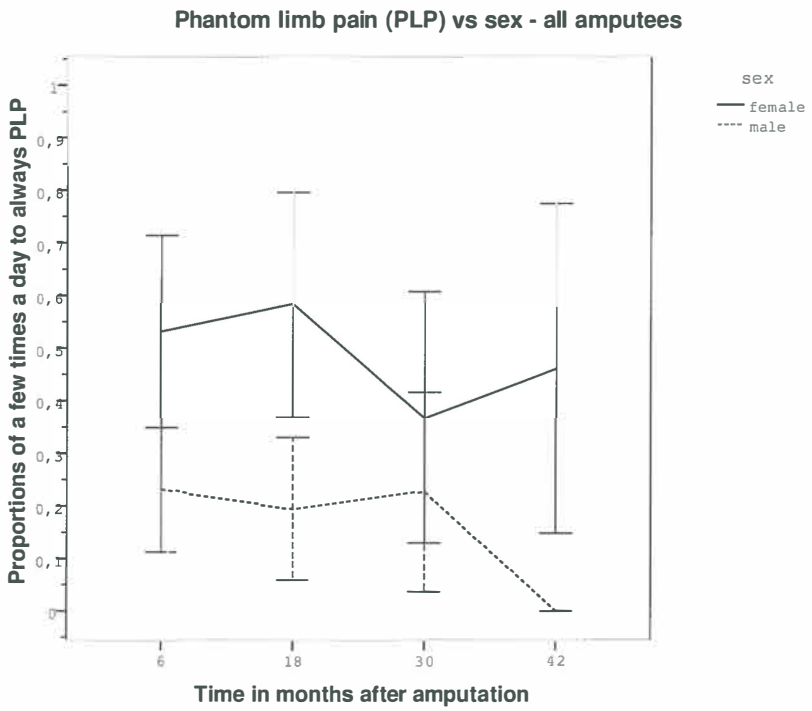
Referred (n=*225*)	*Included in the analyses (included)*	*Drop-outs after inclusion + excluded from study (excluded)*	*Significance of the difference between included and excluded*
% (*n*)	38% (*n*=85)	62% (*n*=140)	
Mean age at amputation	58.2 yrs (sd 17.4)	67.1 yrs (sd 16.0)	$p<0.001$ 8.9 yrs (95%: 4.4 to 13.4)*
Patients			$\chi 2$ $p=0.861$
female	39% (33)	40% (56)	
male	61% (52)	60% (84)	
Reason for amputation			$p<0.001$
PVD	59% (50)	80% (113)	
cancer	14% (12)	11% (15)	
trauma	27% (23)	9% (12)	
Level of amputation			$\chi 2$ $p=0.503$
proximal	29% (25)	36% (51)	
KD	17% (14)	13% (18)	
distal	54% (46)	51% (71)	
Amputation			$\chi 2$ $p<0.001$
upper-limb	14% (12)	1% (2)	
lower-limb	86% (73)	99% (138)	
bilateral	5% (4)		

*Mean difference (CI 95%)

Characteristics, reason for and level of amputation and the proportions of upper- and lower-limb amputees included and, on the other hand, of those who were excluded and/or dropped out after inclusion (within 6 months after amputation) are summarized in table 1. The amputees who were excluded and/or dropped out, were significantly older ($p<0.001$) and underwent amputations because of PVD ($p=0.009$) significantly more often than those who were included in the analyses.

No significant difference was found in sex and level of amputation between the amputees included in the analyses and those excluded from the analyses and/or dropped out.

Figure 2 Proportions - with error bars - of reported PLP over time, categorized by sex.



Upper-limb: In total, 12 of the 14 patients with an upper-limb amputation filled in two or more questionnaires (a preoperative assessment and at least one postoperative assessment). Table 2 shows the characteristics of these 12 upper-limb amputees.

Table 2 Characteristics of the 12 upper-limb amputees included in the analyses.

	Included in the analyses
Patients	
female	58% (7)
male	42% (5)
Mean age at amputation	48.5 yrs (sd 20.43)
Reason for amputation	
PVD	17% (2)
cancer	8% (1)
trauma	75% (9)
Level of amputation	
proximal	58% (7)
distal	42% (5)

Table 3 shows that the percentage of lower-limb amputees with PLP decreased in the course of the time: from 32% at 6 months after amputation to 27.5% (1½ years), 23.5% (2½ years) to 25% at 3½ years after amputation, respectively. In contrast, more upper-limb amputees suffered PLP in the course of time, but the sample is small. As to prosthetic use, upper-limb amputees used their prosthesis hardly ≥ 4h/day. One and a half years and 2½ years after amputation (T2+T3) the highest percentage of lower-limb amputees used their prosthesis ≥ 4h/day (66% and 68%, respectively), but in the course of time this percentage decreased to 56%.
To illustrate the occurrence of PLP over time, figure 2 shows the reported frequency of PLP for all amputees by sex. More women than men experienced PLP a few times a day or more frequently.
The results of the 2-level regression analysis to predict PLP (a few times a day or more frequently against a few times a week or less frequently) are summarized in table 4. Being male, having a lower-limb amputation as well as the time elapsed since amputation, these factors all had a significant protective effect on the frequency of PLP.

Table 3 Percentages and numbers of all amputees as well as a division into lower-limb and upper-limb amputation included in the analyses concerning phantom limb pain and prosthetic use at T1 (6 months), T2 (1½ years), T3 (2½ years) and T4 (3½ years) after amputation, respectively.

All amputees	*T1 (n=85)**	*T2 (n=62)***	*T3 (n=42)*	*T4 (n=18)*
Phantom Limb Pain				
Yes	34.5% (29)	35% (21)	29% (12)	32% (6)
Prosthetic use ≥ 4h/day	43.5% (37)	60% (37)	56% (23)	47% (9)
Lower-limb amputation	(*n*=73)*	(*n*=53)**	(*n*=35)	(*n*=15)
Phantom Limb Pain				
Yes	32% (23)	27.5% (14)	23.5% (8)	25% (4)
Prosthetic use ≥ 4h/day	49% (36)	66% (35)	68% (23)	56% (9)
Upper-limb amputation	(*n*=12)	(*n*=9)	(*n*=7)	(*n*=3)
Phantom Limb Pain				
Yes	50% (6)	78% (7)	57% (4)	67% (2)
Prosthetic use ≥ 4h/day	8% (1)	22% (2)	0% (0)	0% (0)

* Missing data of the PLP of 1 lower-limb amputee; ** Missing data of the PLP of 2 lower-limb amputees. Phantom limb pain: no = a few times a week or less frequently, yes = a few times a day or more frequently.

Table 4 Results of the 2-level regression analysis to predict PLP (a few times a day or more frequently against a few times a week or less frequently).

	β	SE β	OR
Sex (0=female, 1=male)	-2.085	0.697	0.124
Extremity (0=upper-limb, 1=lower-limb)	-1.953	0.932	0.142
Time since amputation (years)	-0.645	0.218	0.525
Constant	2.808	1.002	

β: regression coefficient; SE β: standard error of β ;OR Odds Ratio

Discussion

In this prospective study it appeared that the chance of having phantom limb pain (PLP) was less in men as compared to women, less in lower-limb amputees as compared to upper-limb amputees, and the chance of having PLP decreased over time. Other risk factors, viz. as age, reason for or level of amputation, prosthetic use and, in the case of lower-limb amputees, walking distance, were not associated with having PLP.[1;4;8;10]

Differences between women and men in the way they perceive and experience pain, are well-known.[21-23] Women seem to be more willing to report pain whereas men under-report pain, women are more willing to seek healthcare than men are, and the burden of pain and the frequency of pain attacks in women is greater.[21;23] Biological as well as psychosocial differences have been found to explain sex differences in pain experience, such as differences in body size and skin thickness, hormonal differences and differences in nervous system organization. Furthermore, men and women seem to use different coping styles when in pain, which might explain the differences in pain sensitivity.[22;23] These sex differences in pain experiences can also be expected in limb amputees. This expectation was not always confirmed in previous research on PLP.[3;4;10;15] In contrast, other studies did find that more females experienced PLP, as compared to males or that females reported a higher PLP intensity than men, but no reason was given.[24;25] Our finding that more women than men reported PLP might be related to differences in answering tendencies.

In literature, the estimation of the prevalence rate of PLP for all limb amputees ranges considerably: between 41 to 85%.[1-4] In general, upper-limb amputees show a lower prevalence rate (41 to 59%, with one finding of 82% in 1982) than lower-limb amputees (53 to 85%). Those rates are from cross-sectional studies in which the time elapsed since amputation varied widely, from 3 to more than 15 years. In the only prospective study on upper-limb amputees performed until now, the prevalence rates of PLP between the initial and the follow-up session (within the first six months and 2 to 3 years after amputation) remained consistent (63%).[26] Few longitudinal studies on lower-limb amputees assessed changes in prevalence rates of PLP over time. Jensen found a prevalence rate of 72% at 8 days, 65% at 6 months and 59% at 2 years, while Nikolajsen found a rate of 68% at 3 months and of 73% at 6 months and it is said that the prevalence rate remains relatively constant over 5 years.[10;12] Our findings, however, show that lower-limb amputees have lower prevalence rates of PLP compared to the aforementioned studies (32% at 6 months, 27.5% at 1½ years, 23.5% at 2½ years and 25% at 3½ years, respectively). A reason that our findings in prevalence rates differ from other studies may be the difference in cut-off points for PLP. In our study PLP was dichotomised as present in cases where an amputee suffered from PLP a few times a day or more frequently, and as absent in cases where PLP was experienced a few times a week or less frequently. Our assumption is that, when patients were asked to fill in the questionnaire, they remembered daily PLP better than those who

suffered from PLP less frequently. So it was decided to choose the aforementioned cut-off points for PLP.[9] Furthermore, a difference in prevalence rates of PLP between lower-limb and upper-limb amputees was found in our study, the upper-limb amputees having much higher prevalence rates (50 to 78% in the course of time). It must be remembered that our sample of upper-limb amputees is small. Our prevalence rates of PLP for upper-limb amputees are higher than found by other researchers.[3;26]. A reason for the difference might be that half of the upper-limb amputees were amputated because of CRPS I. These amputations may be associated with a high prevalence of PLP.

To explain PLP, several theories focusing on the peripheral and central nervous system have been developed.[27-30] Insights into brain plasticity and functional Magnetic Resonance Imaging (fMRI) suggest that PLP is a phenomenon related to cortical changes in the brain. At present, it is unknown whether the cortical reorganization is restricted to the hand and arm areas of the motor cortex or whether such reorganization may also be observed in the leg area of the motor cortex. It seems biologically reasonable to assume that a similar reorganization may occur in upper-limb as well as in lower-limb amputees. However, considering the much larger map of the hand and arm on the motor cortex (homunculus), it also seems reasonable to expect that the reorganization after an upper-limb amputation will be much more pronounced than after a lower-limb amputation. The influence of time on cortical reorganization and so on PLP, is not known. Our findings show that, as the time since amputation elapsed, amputees reported PLP occurring less often.

As briefly stated in the introduction, the cause-effect relationship between the experience of PLP and prosthetic use remains controversial and it is not clear how these two phenomena influence each other. Until now, only one prospective study on upper-limb amputees has been performed in which patients were asked after their prosthesis use and after PLP as well as phantom limb sensations (PLS), phantom limb awareness (PLA) and stump pain (SP).[26] In that study it was found that not PLP but PLA may be influenced by the frequent use of a functional prosthesis. The study population, however, was small (n=11).[26] In our study, the relationship between PLP and prosthetic use was analysed and no association between PLP and prosthetic use was found, either.

The strength of our study is its prospective character, and that it has been performed on a substantial sample (*n*=85) with a follow-up to a maximum of 3½ years. In other prospective studies the samples ranged from 21[17] to 58[10] patients

and the drop-out rate ranged from 8%[16] to 43%[31]. Additionally, only one study[10] had a follow-up of 2 years with a drop-out rate of 41% of the original 58 patients, while in the other studies the follow-up did not exceed 1 year.[12;15-18]

A limitation of this study is the selection bias through exclusion and drop-out within 6 months after amputation. The excluded and dropped-out patients were significantly older and underwent an amputation because of PVD more often than the included amputees. Unknown is the PLP frequency of the excluded and dropped-out amputees who are still alive. The length of the follow-up was not the same for all patients; some patients dropped out from the study or died, for other patients the follow-up was limited to 6 months, 1½ or 2½ years because the study ended due to limited financial resources. In future, more prospective studies on upper-limb and lower-limb amputees are needed to examine the relationship between PLP and the different risk factors. Another limitation of this study is that the GQPLA and the GQPAA, the only available questionnaires in Dutch assessing PLP, have not been not tested for reliability and validity. More research is needed to test the (Dutch) questionnaires for reliability and validity.

In conclusion, the results of our prospective study show that protective determinants for PLP are being male, having a lower-limb amputation and the time elapsed since amputation.

Clinical messages

The time elapsed since amputation and the place of amputation (lower limb) were seen to have a protective effect, i.e. the frequency of phantom limb pain proved to be lower.

The percentage of amputees using their prosthesis ≥ 4h/day decreased over time.

More prospective studies on upper-limb and lower-limb amputees are needed to examine the relationship between phantom limb pain and its different risk factors.

Acknowledgments

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Chapter 6

Knee disarticulation: survival, wound healing and ambulation. A historical cohort study[§]

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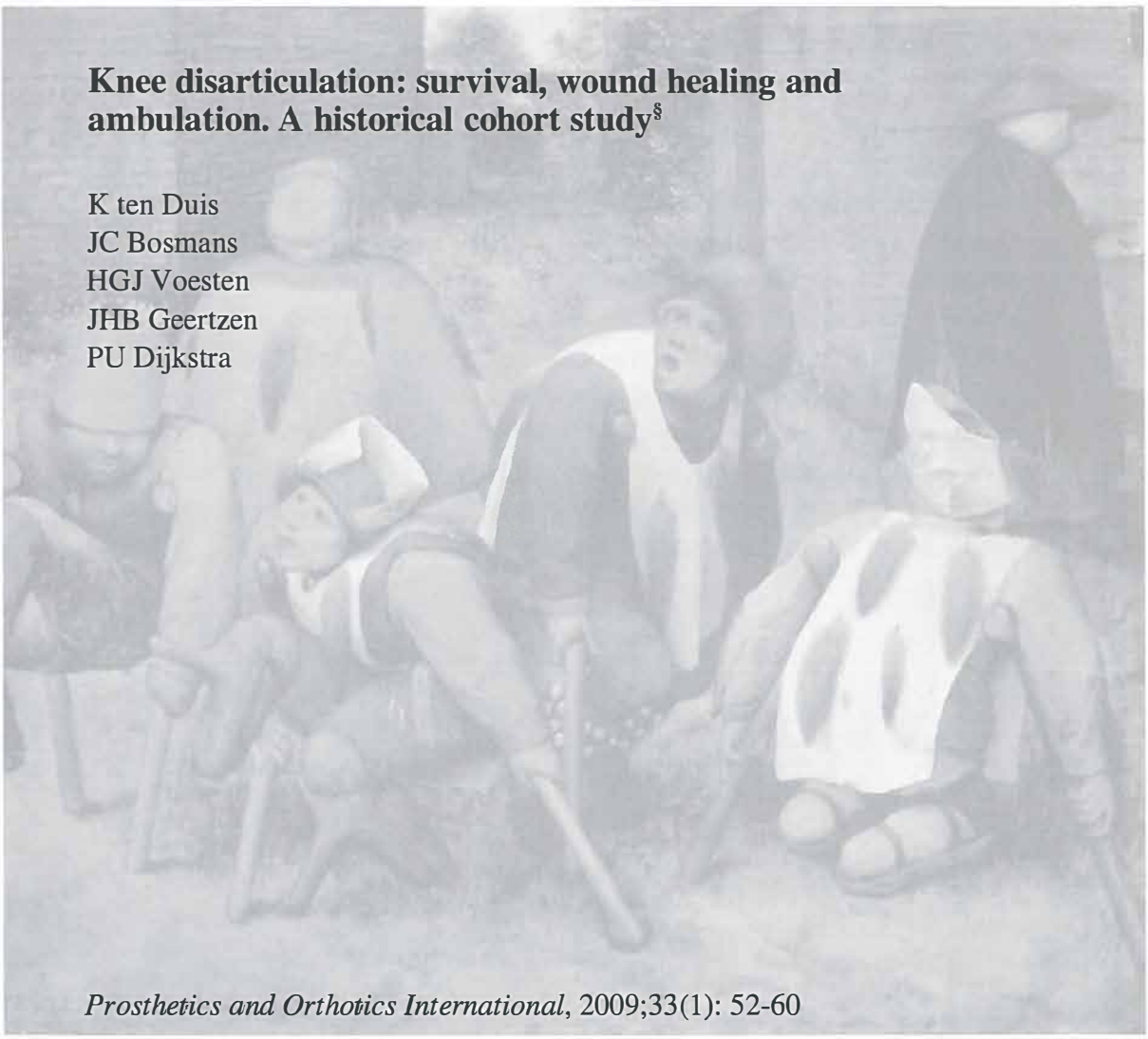


Prosthetics and Orthotics International, 2009;33(1): 52-60

[§]Accidentally, in the original article the term 'historic' instead of 'historical' was used.

Abstract

The aim of this study was to analyse survival, wound healing and ambulation after knee disarticulation (KD). A historical cohort study using medical records and nursing home records was performed. Data included demographics, reason for amputation, concomitant diseases, survival, wound healing, re-amputation and ambulation. Data of 80 patients (71 unilateral and nine bilateral amputees) were available for evaluation. Median follow-up was 9.9 years (IQR: 4.1; 14.3 years). Mean age of amputation was 76.9 (± 9.6) years. Reason for amputation was gangrene in 72 patients. Most common concomitant (96%) disease was peripheral arterial disease (PAD). Survival after 1, 6 and 12 months was 87%, 65% and 52%, respectively. Delayed wound healing occurred in 42% (n=16) of the patients with two or three concomitant diseases and in 15% (n=6) of the patients with no or one concomitant disease. Transfemoral re-amputation was performed on nine (12%) patients. Of the 61 discharged KD amputees, 36 (59%) were provided with a prosthesis. Eventually, 21 (34%) patients became household walkers.

Introduction

Despite continuing medical progress and improvements in general living conditions, we increasingly find ourselves faced with elderly, multiple ill patients in whom the limits of reconstructive procedures for peripheral arterial disease (PAD) have been reached. These patients account for more than 90% of all limb amputations.[1-3] When vascular intervention in lower limbs by non-invasive or operative treatment has failed, lower limb amputation may be the only option to save the life of a patient. After consultation with a rehabilitation team the surgeon then has to decide on the level of amputation, bearing in mind that maintenance of ambulation is an important factor associated with preserving independence.[4]
An important goal in the care of the patient who requires amputation is to retain the knee joint, given its contribution in preserving ambulation.[5] Ideal stump length for transtibial amputation (TTA) is approximately 15 cm below the knee joint.[6] Whenever this margin is not feasible, or an adequate soft-tissue envelope of mobile muscle or full-thickness skin in areas of load transfer can not be retained, a more proximal knee disarticulation (KD) or transfemoral amputation (TFA) should be considered.
Before the use of surgical anaesthesia, the advantage of KD was the speed of surgery and the limited amount of associated bleeding (as this technique does not violate or transect any muscle bellies). Additionally, KD has the advantage of maintaining the cartilage barrier which potentially reduces the risk of infection, which is especially important in compromised patients.[7-9] Clinically, the most important advantages of KD procedures are direct load transfer to the residual limb with enhanced walking independency and less energy consumption compared to TFA.[7,10-13] KD combined with polycentric (exo-skeletal) prosthetic joints, can offer considerable walking stability in geriatric patients.[9,12]
Although Smith described a KD as early as 1824[14,15], it initially never gained the popularity the TFA did, because of assumed greater risk of delayed wound healing with necrosis and/or infection leading to re-amputation.[13,16,17] Ever since, surgical techniques have used a variety of surgical flap designs to reduce these problems.[7,13,16,18-22]
Despite increasing popularity during the past 20 years[23], KD still receives little attention.[16] Yet, enhanced stability of walking (better mobility) after KD, as well as lower mortality rates as compared to TFA suggests a more prominent role of KD.[12,13,24] Potential ambulatory patients who have a substantial knee-flexion

contracture can be successfully fitted with and use a prosthesis after KD. In non-ambulatory patients muscle imbalances in transtibial amputees may induce knee-flexion and hip contracture, whereas a hip flexion-abduction contracture may result following TFA. Patients with knee-flexion contractures are prone to pressure ulcers on the distal stump. The stump of the transfemoral amputee provides little support for sitting in a chair and the lever arm is inefficient for use in transfers.[8] A short stump results in decreased trunk stability and limited ability to lean forward in case of bilateral TFA. Concluding, KD can be an appropriate alternative for TTA and TFA, depending on patient and treatment intentions.[25-27]
The aim of this study was to analyse survival, wound healing and ambulation after KD in patients predominantly suffering from peripheral arterial disease.

Methods

Design and setting
A historical cohort study was performed using medical records and nursing home records. Of all lower-limb amputations all KDs between July 1989 and March 2006 were selected. One surgeon (HV) in a single 340-bed community hospital in the north of the Netherlands carried out all amputations. The medical records and nursing home records included data on patient demographics, concomitant diseases such as diabetic mellitus, cerebrovascular diseases, cardiovascular diseases and systemic diseases (e.g., rheumatoid arthritis), reason for amputation, previous ipsilateral revascularisation, previous ipsilateral amputations, and postoperative data, including survival, wound healing, infection, re-amputation transfemoral, dressing method, hospitalisation time, discharge destination, prosthesis fitting and ambulation level. Data from the records were entered in a database. Dates of death were verified using the hospital's computerised patient records or death certificates derived from municipal offices. Data concerning prosthesis fitting and ambulation were retrieved from records of the rehabilitation centres and nursing homes.

Statistical analysis
Descriptive statistics and χ^2 analyses were performed using SPSS version 12.0 for Windows.

Results

Patients

During the study period 84 consecutive patients underwent 93 KDs using sagittal flaps. Data of four patients (four amputations) were excluded from the study because of incomplete records, leaving 80 patients for evaluation. Median follow-up was 9.9 years (IQR: 4.1; 14.3). Descriptive statistics of patients, reason for amputation, concomitant diseases and previous ipsilateral procedures are summarised in table 1.

The mean age of women (79.0 ± 9.9) at the time of amputation was slightly higher than that of men (74.4 ± 9.2). The median interval between the last vascular reconstruction and the KD was 8.9 months (IQR: 1.1; 52.6). The median interval between a previous ipsilateral amputation and the KD was 3.4 months (IQR: 1.6; 20.4). Median hospitalisation time was 36.5 days (IQR: 17; 68.8).

Survival

Three (4%) patients died within three days after the amputation of cardiopulmonary complications and renal failure. Overall, 10 (13%) patients died during hospitalisation. Survival after 1, 6 and 12 months was 87%, 65% and 52%, respectively. Survival of patients with a bilateral KD was considerably poorer than of patients with a unilateral amputation (figure 1).

Table 1 Descriptive statistics concerning patients (n=80), reason for amputation, side of amputation, concomitant diseases, previous ipsilateral procedures and postoperative dressing methods.

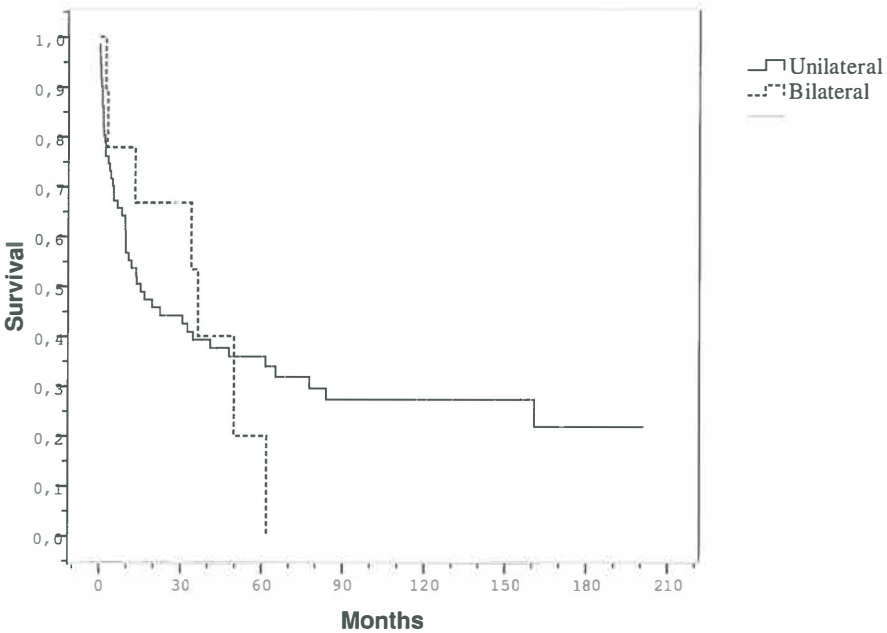
Variables	
Age (years) mean (sd)	76.9 (9.6)
	% (n)
Males	56% (45)
Amputation reason	
gangrene	90% (72)
Infection	4% (3)
acute vascular insufficiency	4% (3)
vascular disease stage III	1% (1)
knee contracture	1% (1)
Amputated side	
right side	39% (31)
left side	50% (40)
bilateral*	11% (9)
Concomitant diseases	
peripheral arterial disease	96% (77)
cardiovascular disease	64% (51)
diabetes mellitus	53% (42)
cerebrovascular disease	31% (25)
systemic diseases	5% (4)
Number of concomitant diseases	
≤1 co-morbidity	49% (39)
≥2 co-morbidities	51% (41)
Previous ipsilateral procedures	
revascularisation	29% (23)
amputation	18% (14)
level of the foot**	10% (8)
transtibial	8% (6)
Postoperative stump dressing***	
elastic bandage	68% (54)
plaster of Paris	33% (26)

*One patient underwent a bilateral amputation in one session. The other patients were amputated on the contralateral side in an alternate phase.

** One patient underwent a transtibial amputation at a later stage.

*** Due to rounding off, the percentages exceed 100%.

Figure 1 Survival after knee disarticulation in months.



Wound healing

Because three patients died in the very early post-operative phase, data of these patients were excluded from the wound healing analysis, leaving a data set of 77 patients for analysis.

In 65 (84%) patients wounds had healed. In 55 (71%) patients wounds had healed primary. In 10 (13%) patients wounds healed, but delayed (table 2). Of these patients 6 (8%) had developed a wound infection (determined by positive culture or prescription of antibiotics aimed at an infection of the stump wound). Two patients were treated with sterile maggots and four patients underwent débridements. Nine (12%) patients were re-amputated transfemorally. Six amputations were performed for necrosis, one for pressure ulcers and one because of a wound infection. Three (4%) patients died before their wounds had healed. Of the patients with two or three concomitant diseases 42% (16/38) had a delayed wound healing. Of the

patients with no or one concomitant disease 15% (6/39) had a delayed wound healing. This difference, 27% (95% CI: 7-44%) is significant (p=0.009). Diabetes mellitus was not associated with delayed wound healing (p=0.678). We did not look into the relationship smoking and delayed wound healing. No significant difference was found in delayed wound healing between the patients receiving an elastic bandage (31%, n=16) compared to the group receiving plaster of Paris (23%, n=6) (p=0.447).
After a median interval of 2.1 months (IQR: 1.0; 18.7), nine patients (12%) were amputated again contra-laterally at KD level due to PAD. Of the patients who had an ipsilateral amputation at the level of the foot or tibia before KD, none needed a TFA in an alternate phase.

Table 2 Statistics concerning wound healing (n=77), discharge (n=80), prosthesis fitting (n=61) and ambulation (n=36).

Variables	*% (n)*
Wound healing	
primary	71% (55)
delayed	13% (10)
no wound healing resulting in TFA	12% (9)
died before healing	4% (3)
Discharge destination#	
nursing home	58% (46)
rehabilitation centre	19% (15)
rehabilitation day-care	8% (6)
home	4% (3)
died in hospital	13% (10)
Discharged KD amputees	
provided with a prosthesis	59% (36)
not provided with a prosthesis	18% (11)
missing data	23% (14)
Ambulation with prosthesis	
household walkers	58% (21)
wheelchair-bound	31% (11)
missing data	11% (4)

#Due to rounding off, the percentages exceed 100%.

Discharge and ambulation

Ten (13%) patients died in hospital. Forty-six (58%) patients were rehabilitated in a nursing home and 15 (19%) patients went to a rehabilitation centre as in-patients. Six (8%) patients received day-care rehabilitation (out-patients) and three (4%)

patients went home without rehabilitation treatment.Of the 61 discharged knee disarticulation amputees (transfemoral amputees (n=9) and patients deceased in hospital (n=10) were not included in this analysis), 36 (59%) patients were provided with a prosthesis and 11 (18%) were not. For 14 (23%) patients these data were not available. In total 34% (21 of 61 discharged knee disarticulation amputees) became household walkers, 11 (18%) were wheelchair-bound. Four patients were able to walk more than 500 m with the aid of a walker or crutches. For four patients data on ambulation status were not available (table 2).

Discussion

Patients with a bilateral KD had a poorer survival using sagittal flaps after 1, 6 and 12 months (87%, 65% and 52%, respectively) compared to those amputated unilaterally. Delayed wound healing (29%, n=22) was significantly related to two or more concomitant diseases. Wound healing occurred in 84% of the patients. Of the discharged knee disarticulation amputees, 36 (59%) were provided with a prosthesis. Twenty-one (34%) patients became household walkers.

Our survival rate of 87% one month after KD was favourable compared with the 80% survival found previously for a similar procedure[28], also because in the latter study the mean age of the patients was 72 years whereas in the current study the mean age is 79 years. Our results seem to be comparable with the literature regarding the in-hospital 48-day survival after gastrocnemius flap procedures (ranging from 78% to 91%).[3,19,23,28] Twelve months survival of 52% in our study could not be compared, because previous studies used different follow-up periods.[19,23-25,29,30] A survival rate of 48% after 26 months in the study of Kock *et al.* was more favourable than our results, but the mean age (66.7 ± 11.3) of their sample (n=66) was statistically significantly (p<0.001) lower than our sample.[23] Clinically, our data indicated that 52% of the patients survived after 12 months who would otherwise have been deceased because of gangrene. These patients were critically ill and an amputation was their only hope to extend their lives.

Survival after bilateral KD was considerably poorer compared to survival after unilateral KD (figure 1). Presumably, these patients were more ill; the contralateral KD after a median period of 2.1 months and their poor survival were a consequence of this illness.

Primary wound healing rate of 71% in the current study was identical with the rates found previously[23,28], but, as mentioned before, the mean age of amputation in those studies was considerably lower. Two or more concomitant diseases influenced wound healing considerably. Diabetes as a single concomitant disease did not influence wound healing as was found previously.[31]

For many years, TFA was recommended because of the supposed better wound healing compared to that at a more distal level.[5,13] However, pooled data from large series showed a total healing rate of approximately 85% in TTA procedures, which was better than rates found previously for TFA procedures.[5] In comparable samples sizes for KD procedures, different wound healing rates ranging from 40-80% are described.[13,19,23-25,29,30] Comparatively, a primary healing rate of 71% and a secondary healing rate of an additional 13% in this study were identical with results in other KD procedures and almost equal with those found for TTA procedures. Thus, assumed delayed wound healing is not a reason for performing an initial TFA to be sure of better healing at a more proximal level than KD.

Re-amputation at a transfemoral level was necessary in only nine (12%) patients. Compared to re-amputation rates after conventional KD procedures (ranging from 19-40%)[24,30,32], our results seem favourable. Compared to KD procedures using a gastrocnemius flap, our results are similar to those of Klaes and Eigler (1985)[19] and of Kock *et al.* (2004).[23]

At present, no established test can predict the optimal level of amputation, related wound healing and level of ambulation after amputation. Predicting whether an amputation wound is likely to heal is challenging, since patients who are predicted to have adequate wound healing could be ambulatory immediately after surgery, which is likely to improve both their physical and psychological state.[33] Skill and experience of the surgeon are still important factors in determining the level of amputation. It is notable that of the six patients who had a KD after TTA, none developed an infection or wound healing problem requiring further revision to TFA, thus the amputation level was appropriate.

In order to advance recovery, post-operative rigid dressings are strongly recommended, because of local protection of the wound and the prevention of oedema and knee flexion contractures.[34,35] However, the optimal stump dressing method after KD has not been studied well. Nevertheless, some reviews reveal a trend in favour of rigid and semi-rigid dressings for achieving stump healing and reduction of stump volume. Primary wound healing after TTA occurs earlier in case of rigid dressings.[34,35] In the current study, no significant difference in wound

healing between patients postoperatively treated with soft dressings and patients treated with rigid dressings was found.

Only a limited percentage (45%) of the original 80 amputees could be provided with a prosthesis and only 26% became ambulatory. These results do not seem too favourable at first glance compared to patients in other studies (29-77%).[23,24,28] However, our patients were considerably older compared to other studies. Furthermore, other studies relate the rates of prosthesis provision and ambulation to the number of patients discharged. If we calculate our data accordingly, 59% of the patients were provided with a prosthesis and 58% of those became household walkers. After this calculation our data still remain somewhat less favourable.

A limitation of our data was that data of 14 patients with respect to prosthesis provision and four with respect to ambulation level could not be retrieved. Our results only remain less favourable if all missing data concern patients who are not provided with a prosthesis and are wheelchair-bound.

Another limitation of our study was the retrospective design. Medical records of four patients were not complete. Nursing home records of the rehabilitation facilities were of moderate quality. Many data were missing, as mentioned above. Further, the data from the medical records and the nursing home records had to be interpreted and sometimes arbitrary decisions had to be made. In case of such decisions two observers in consensus decided what was to be entered in the data base.

Clinically, amputation should be regarded as a reconstructive procedure that is designed to restore function and attempt to allow the patient to return to an independent lifestyle. Ambulation after amputation, with or without the use of aids, represents a major achievement. Whenever the knee joint cannot be saved a TFA should be avoided in favour of KD. There are no grounds for performing an initial TFA to spare the patient an additional operation. Although quality of medical care and therapeutic options are improving every year, the one year survival of knee disarticulation amputees is low.

Acknowledgments

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Chapter 7

Claimed walking distance of lower limb amputees

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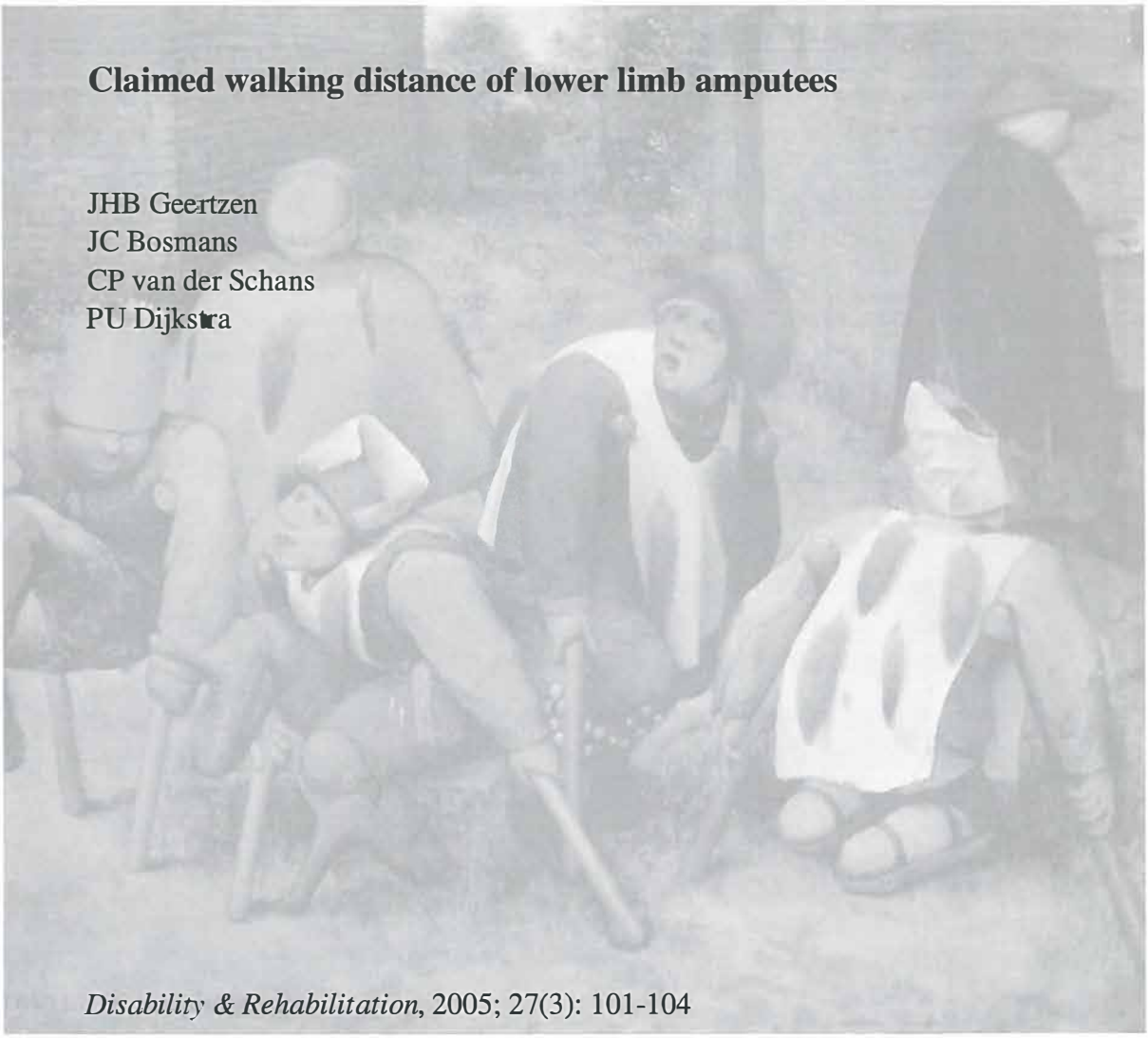

Disability & Rehabilitation, 2005; 27(3): 101-104

Abstract

Purpose: Walking ability in general and specifically for lower limb amputees is of major importance for social mobility and ADL independence. It determines prosthesis prescription. The aim of this study was to mathematically analyse factors influencing claimed walking distance of lower limb amputees of 500 m or more.
Methods: A total of 437 patients returned two questionnaires: the Groningen Questionnaire Problems after Leg Amputation, in which walking distance was assessed, and the RAND-36.
Results: The chance of walking 500 m or more reduced when a transfemoral amputation was performed. The chance reduced even more when phantom pain or stump pains were present. If the amputation was performed because of vascular disease or because of vascular problems because of diabetes the chance reduced again. Independently of these factors, age reduced the chance of walking 500 m or more.
Conclusion: The chance of walking 500 m or more reduces with increase in age and a more proximal amputation. The chance reduces even further when the amputation is performed because of diabetes or a vascular disease and also if phantom pain and or stump pain is present.

Introduction

Walking ability in general and specifically for amputees is of major importance for social mobility. Walking enables a simple and directly available means of transportation. Minor limitations in walking distance may limit social interactions partially if no other means of transportation are available. Larger limitations in walking distance may hinder shopping and recreational activities and major limitations in walking distance may not only restrict outdoor activities but also indoor activities. In this respect, walking distance is an important factor in life: it enables ADL independence.

Walking distance is critical in lower limb amputees, especially in elderly amputees suffering from co-morbidity such as diabetes mellitus, osteoarthritis or vascular disease. However, these elderly amputees with co-morbidity are the majority of the total group of amputees; about 80% of amputees are 60 years or older.[1]

After lower limb amputation, adequate prostheses prescription is necessary to be able to walk, but only 48% of elderly amputees are fitted with a prosthesis.[1] Further, the ability to walk depends on the possibility of fitting a prosthesis, which in turn depends partially on co-morbidity.[2,3] Reciprocally, walking distance of a patient determines, amongst other things, the properties and components of the prosthesis prescribed. In the process of prescribing a prosthesis, a patient is usually asked for her or his ability to walk a distance. It is estimated that a walking distance of 500 m or more enables adequate ADL independence and is a positive determinant with respect to quality of life in amputees.[4] With this distance of 500 m, shops in the neighbourhood can be visited either by walking or by walking from a parked car to the entrance of the shop and still being able to walk in the shop.

If the walking distance exceeds 500 m, the requirements of the prosthesis are more demanding: such as multiaxis ankle, dynamic foot and a multibar linkage knee.[5,6] If the walking distance is less than 500 m, the requirements of the prosthesis are less demanding and more focussed on stability. Thus, information given by the patient about his or her walking ability and walking distance is important for the requirements of the prosthesis. Further, prostheses prescription and thus also walking distance depend on the age and the profession of the amputee, the reason for amputation and the level of amputation, stump condition, co-morbidity, stump pain and phantom pain.[7-9] The influences of the different variables on walking distance have been analysed univariately in different studies, but the cumulative effects of these variables on walking distance are seldom analysed.

The aim of this study was to analyse, mathematically, the walking distance claimed by lower limb amputees of 500 m or more. In the analysis, age, level of amputation, stump pain, phantom pain and reasons for amputation are included.

Methods

Patients with a lower limb amputation were identified in the database of an orthopaedic manufacturing company (OIM Haren, the Netherlands). This database included patients who were referred by their physician (mostly medical specialists in Physical Medicine & Rehabilitation) to the orthopaedic manufacturer since 1 January 1993, for prosthesis fitting because of a major lower limb amputation. First, the manufacturer sent a letter to all patients who were registered in the database (n=1436), in which they were informed about the study and in which they were invited to participate. In total, 536 (37%) patients returned positive replies. These patients were sent a questionnaire. Of this group, 437 (82%) patients returned the questionnaire. The questionnaire, the Groningen Questionnaire Problems after Leg Amputation (GQPLA) is a modified version of the questionnaire we used in an earlier study of upper limb amputees.[4,10,11] This questionnaire assesses reason and level of amputation, presence of phantom pain and stump pain, and walking distance (500 m or more). Demographic questions are also asked. To verify the answers concerning walking, the RAND-36 was also sent simultaneously.[12] The RAND-36 is a 36-item Health Survey and is similar to the MOS-36. The RAND-36 has nine subscales: physical functioning (walking, stair climbing, running, ADL), social functioning (social contacts), role limitations (restriction of ADL due to physical problems), role limitations (restriction of ADL due to emotional problems), mental health, vitality, pain, general health perception and health change.

Stump pain was operationally defined as any painful sensation in the stump. Phantom pain was operationally defined as any sensation in the amputated part of the extremity that is so intense that it is experienced as painful.[10,13]

Descriptive statistics, correlation between physical functioning of the RAND-36 and the claimed walking distance assessed in the GQPLA and multivariate logistic regression analyses were performed in SPSS version 9.0 for Windows. A multivariate logistic regression was used to analyse the relationship between two ore more continuous or categorical explanatory variables and a single dichotomous

response variable, in this study, the ability to walk 500 m or more. The ability to walk 500 m or more was predicted on the basis of presence or absence of the explanatory variables, age, and transfemoral or transtibial amputation, amputation due to vascular reasons or diabetes, phantom pain and stump pain. For a detailed example of the calculations the reader is referred to Dijkstra *et al.*[11]
From the results of the regression analysis, the chance of walking 500 m or more was calculated for different combinations of explanatory variables.

Results

Table 1 summarises the demographics of the amputees and amputation characteristics.
Phantom pain was present in 80% of the lower limb amputees. Of the subjects experiencing phantom pain, 70% experienced phantom pain at least a couple times per month. Stump pain was present in 68% of the amputees.
The correlation (Spearmans ρ) between physical functioning of the RAND-36 and the claimed walking distance assessed in the GQPLA was 0.73 ($p<0.001$). For the regression analysis, only the patients with the transtibial and the transfemoral amputations were included, because these patients groups were the largest two groups. The regression coefficients are summarised in table 2. The regression model predicted 73% correctly.
Figure 1 presents the chance of walking 500 m or more for different age groups and different combinations of explanatory variables. For example, a transtibial amputee of 60 years and suffering from phantom pain or stump pain has a 78% chance of walking 500 m, and if the age of the same patient was 80 the chance would be reduced to 55%. However, for a transtibial amputee without phantom pain, these chances would be 88 and 73%, respectively.

Table 1 Reason for amputation, amputation type and age and duration of being amputated in lower limb amputees.

	% (n)
Patient characteristics	
Age, mean (SD)	65.2 (15.1)
Duration of being amputated (years), mean (SD)	17.9 (17.9)
Males	71 (302)
Females	29 (125)
Reason for amputation	
Vascular disease	28.8 (126)
Diabetes mellitus	20.6 (90)
Trauma	34.3 (150)
Cancer	8.7 (38)
Congenital	2.3 (10)
Other	4.3 (19)
Amputation type	
Pelvis	0.5 (2)
Hip	2.3 (10)
Transfemoral	28.1 (122)
Knee exarticulation	7.8 (34)
Transtibial	57.1 (248)
Ankle	2.5 (11)
Others	1.6 (7)

Data do not add up to 437 because some data were missing.

Table 2 Regression coefficients.

Variables	β
Transfemoral (yes/no)	-0.859
Age (per year)	-0.054
Stump pain (yes/no)	-0.757
Phantom pain (yes/no)	-0.772
Amputation reason vascular or DM (yes/no)	-1.279
Constant (transtibial)	5.303

Figure 1 Chance of walking 500 m or more.

TT, transtibial amputation; TF, transfemoral amputation; PP, phantom pain; SP, stump pain.
The categories marked with V are the amputations are performed due to a vascular disease or diabetes mellitus. The other amputations were performed because of trauma, oncological disease or were congenital. Note the considerable reduction in the chance of walking 500 m or more with an increase in age for all combinations of explanatory variables. The difference in influence of transtibial amputation compared to transfemoral amputation is also large, and this difference increases with an increase in age. Because the regression coefficients for stump pain and phantom pain were about the same (table 2), the influence of stump pain and phantom pain on the chance of walking 500 m or more is not presented separately.

Discussion

The chance of walking 500 m or more reduces with increase in age and a more proximal amputation. The chance reduces even further if the amputation was performed because diabetes or vascular disease is present, and also if phantom pain and or stump pain is present.
The regression coefficients of phantom pain and stump pain were almost identical. Therefore, the influence on walking distance of these variables is not presented separately because this would have resulted in largely overlapping lines. Further, we restricted the analysis to transfemoral and transtibial amputations for two reasons: these amputations were the largest groups. Moreover, energy expenditure for walking with a transfemoral or a transtibial amputation has been investigated

extensively.[14,15] The energy expenditure is larger for the transfemoral amputation. Even less is known with regard to the energy use during walking for other types of amputation (pelvic, knee exarticulation).[16]

The results of our study can be used to predict the chance of walking 500 m or more for lower limb amputees. These data can be a helpful in prescription of prostheses.[17] In the provision of a prosthesis, the future of the amputee should be matched with the prosthetic components and the use of the whole prosthesis. It is recommended that the functional ability (including walking distance) of the amputee forms the starting point in formulating the prescription of a lower limb prosthesis.[18,19] Prescription of the specified components of the prosthesis depends on the age of the amputee, co-morbidity, mental condition, etc. In our calculations we used pain, age, level of amputation and co-morbidity (diabetes mellitus or vascular reason for amputation) as the explanatory variables.

A restriction of our study was that we did not actually measure the walking distance. However, in the process of prescribing a prosthesis, the patient is always asked to estimate their walking distance. Only during prescription of the first prosthesis is a physiotherapist counselled. To validate the claimed walking distance we also sent the RAND-36 with the subscale 'physical functioning'. The RAND-36 is a short version of the RAND Health Insurance Study Questionnaire and it is similar to the MOS SF 36.[12] The correlation between both was 0.73. This correlation supports the validity of the claimed walking distance considerably.

Another weakness of our study is the selection bias, only amputees who were referred to the orthopaedic manufacturer were included in the study. In our study group, we have a rather large percentage of traumatic amputees (34%) who are usually healthier than vascular patients, and thus are expected to walk a larger distance, as is found in the regression analysis with a larger chance.

Conclusions

The chance of walking 500 m or more reduces with increase in age and a more proximal amputation. The chance reduces even further when the amputation is performed because of diabetes or vascular disease, and also if phantom pain and or stump pain is present.

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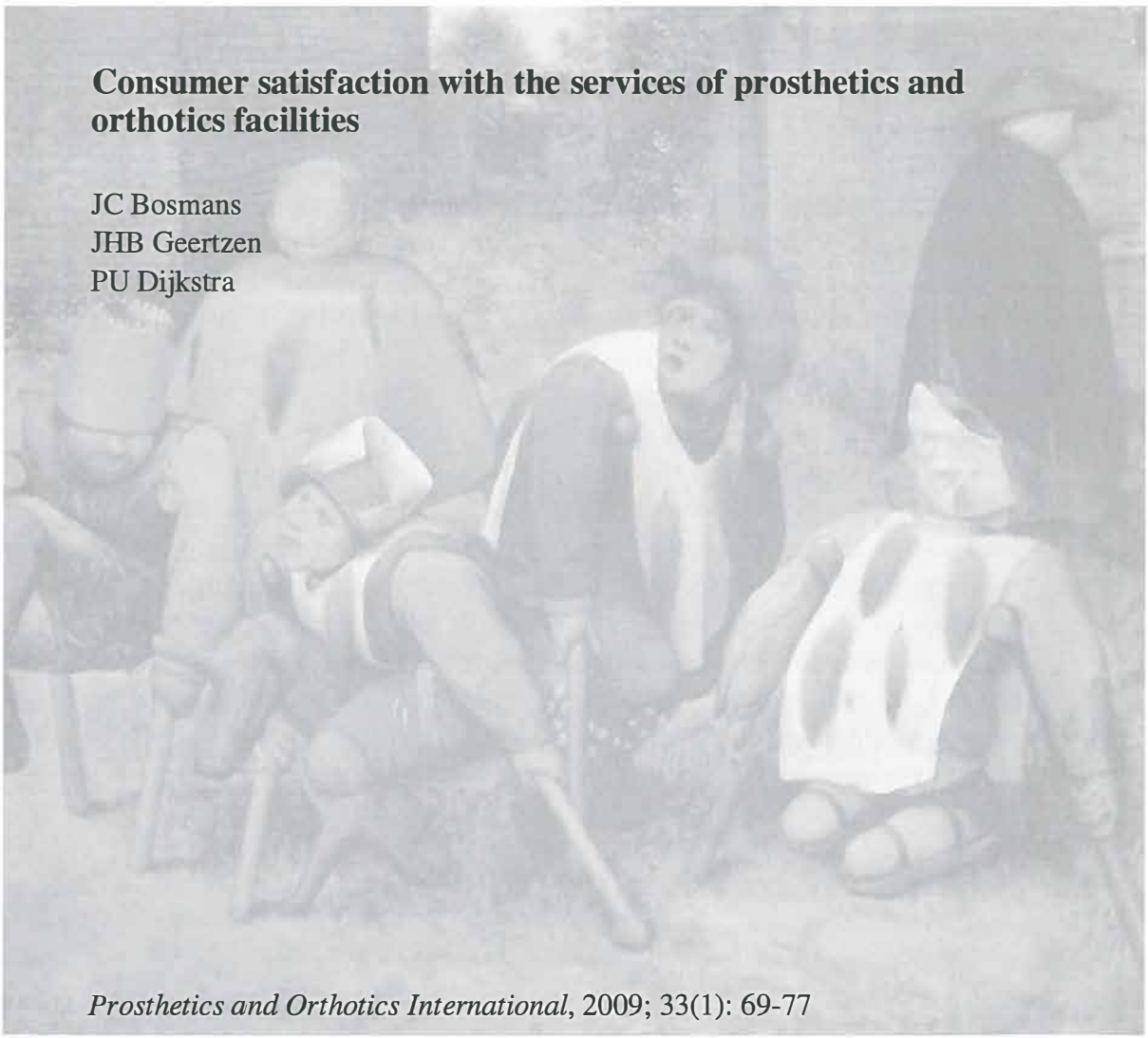
Chapter 8



Consumer satisfaction with the services of prosthetics and orthotics facilities

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Abstract

Consumer satisfaction with the services provided in a prosthetics and orthotics (P&O) facility has seldom been studied. The aim of this study was to analyse consumer satisfaction regarding the services provided by 15 P&O facilities in the Netherlands.

Consumers (n=1,364) of these P&O facilities who were fitted with a prosthesis, orthopaedic shoes, an orthosis, or another device, were asked to rate the overall services provided and whether they were satisfied with the device provided and its delivery time. Additionally, they filled in a modified SERVQUAL questionnaire (see Appendix). Consumers gave the service provided by P&O facilities a mean overall rating of 8.1. The highest ratings were given by consumers fitted with a prosthesis (mean overall rating of services: 8.4). In total, 78% of the consumers were satisfied with the device provided and 93% with the delivery time. The results of our study showed that, on the SERVQUAL, 50% of the statements fulfilled the criteria for a satisfactory quality of the services. The overall consumer rating of the service provided by P&O facilities is high and depends on the device provided. The outcomes on the SERVQUAL were moderate. In future, it is important to study consumer satisfaction more extensively in order to improve the quality of P&O services in daily practice. Additionally, specific questionnaires need to be developed to measure all aspects of prosthetic and orthotic care, with the aim to improve the services.

Introduction

In health care, quality of care is playing an increasingly important role: consumers are becoming more critical, they become better informed about care through the internet and the standard of care is developing rapidly. Additionally, insurance companies demand greater quality in the products they are paying for. To measure quality of care several instruments have been developed, but the exact construct of "quality of care" is not clear. As a result, there is a search for a theoretical concept to develop a (new) framework for measuring quality of care.[1-5]

In the case of limb amputees, different questionnaires[6-9] have been used in order to assess the experiences of people wearing a prosthesis. These questionnaires focus on the quality of life or the satisfaction of the amputee with a certain prosthesis or with the quality of care. A better quality of care may result in a greater satisfaction with the prosthesis or a better use of the prosthesis. In this respect, quality of care includes: (i) the technically correct manufacturing of the prosthesis, as well as the prosthesis' cosmetic aspects and comfort during use; (ii) the service provided to consumers, such as a consumer oriented approach, delivery and waiting time; and (iii) the appearance of the prosthetics and orthotics (P&O) facility, its equipment, privacy, and parking spaces. Specific amputee satisfaction with the prosthesis is often assessed; however, specific satisfaction with the services provided in a P&O facility is seldom assessed. To the best of our knowledge only Heinemann[7] developed an instrument in which consumer satisfaction about the services provided is measured as well. However, no results have been published so far.

In 2002 consumer satisfaction with the services of four P&O and orthopaedic shoes facilities in the north of the Netherlands was studied.[10] The study analysed the services of P&O facilities in general, as well as the consumers' impressions of the facilities' priorities in the services provided and consumer satisfaction with these services. As a result of the outcomes showcases with information brochures about the products of the facilities were installed. Waiting rooms were furnished with new chairs and reading tables. Additionally, complaint books were made available and a complaint committee was installed. These changes were made across the four facilities investigated, very soon after the results became available. In the course of time, changes were made across the other facilities, too.

Data were collected in 2002 using a modified version of the SERVQUAL instrument.[11,12] This instrument measures both consumer perceptions and expectations of the quality of the service given. SERVQUAL has been used to

assess patient satisfaction in different health care environments such as nursing care, dental health care, medical education and medical service.[13-18] In 2005 the management team of 15 P&O facilities spread over the Netherlands, including the four facilities studied in 2002, decided to repeat the study. Their purpose was to evaluate whether the improvements made on the basis of the outcomes of 2002 in the different facilities had indeed changed the quality of service. This decision gave us the unique opportunity to set the outcomes of 2002 and 2005 side by side.
The aim of this replication study was to analyse consumer satisfaction regarding the services provided by P&O facilities, using a modified SERVQUAL questionnaire, and to compare the outcomes of 2005 with those of 2002.

Methods

Between September and October 2005, consecutive consumers, visiting one of the 15 P&O facilities of the OIM-group in the Netherlands, in order to be fitted with a prosthesis, an orthosis, orthopaedic shoes, shoe inlays, prefab shoes, a corset, or stockings were asked to participate in the study. As in 2002, patients were asked to fill in a questionnaire during their visit. In the case of young consumers, their caregivers were asked to fill in the questionnaire.
Prior to the study it was thought that, in order to obtain a sufficiently large sample, about 25 consumers per facility per device supplied in that facility should be asked to participate. It was estimated that the total number of 2,375 participants would be feasible. The inclusion criterion was that consumers or their caregivers were able to read and write Dutch.
Data were collected, using a modified version of the SERVQUAL instrument (questionnaire in appendix). Because there was a strong inter-item correlation in the SERVQUAL questionnaire used in 2002, the questionnaire was shortened from 30 statements to 16 statements.
Consumers were asked to comment twice on all 16 statements: once with regard to their rating of importance and once with regard to their actual experience. An example of such a statement is: "The P&O facility delivers as agreed". On a five-point Likert scale the possible answers were "This statement is very important – important – hardly important – unimportant – totally unimportant to me", and "My experience with the P&O facility is very good – good – indifferent – bad – very bad or I am unable to answer because I have no experience with this specific

statement". The criterion for a satisfactory quality was fulfilled if ≥85% of the consumers rated their "experience" of a certain statement on the SERVQUAL equal to or higher than their rating of its "importance".
Furthermore, consumers were asked to fill in their sex and age, the time (in years) they had been using an orthopaedic device, their satisfaction with its delivery time and with the device itself (yes or no). No other private information was asked for. Finally, consumers were asked to give the P&O facility an overall rating regarding the services provided on a scale of 1 to 10, with "1" being the poorest possible rating and "10" being the highest possible rating.
The management of the OIM-group wanted to assess consumer satisfaction of their facilities as they intended to improve the quality of their services to consumers. Approval of an ethical committee was not needed and hence not asked for. The data base with anonymous results of the assessments was made available to the authors.

Statistics
Statistical analyses were carried out in SPSS 14.0 for Windows, using descriptive statistics. T-tests for independent samples and ANOVA were used to analyse differences between groups regarding interval data, and χ^2 tests were used regarding categorical data. *P*-values <0.05 were considered to be statistically significant. All analyses concerned all consumers in 2005 (2005-all group) and these results were compared with the results of 2002 (2002-group). Additionally, analyses concerned consumers of the same four facilities as studied in 2002 (2005-4 group), and these outcomes were compared with the results of 2002 (2002-group).

Results

A total of 1,364 consumers (2005-all group) filled in the questionnaire. In 46% of the questionnaires all statements were filled in. The questions most frequently filled in (97%) were those about sex and age. The statement "Reachable by means of public transport" was filled in by 44% of all consumers.

Table 1 Percentages and numbers of sex, age groups and devices provided in the different groups studied.

	2005-all (n=1,364)	*2005-4 (n=380)*	*2002 (n=496)*	*Significance of the difference 2005-all and 2002*	*Significance of the difference 2005-4 and 2002*
Sex % (*n*)				0.066	0.012
male	39.2 (517)	42.9 (159)	34.4 (167)		
female	60.8 (803)	57.1 (212)	65.6 (318)		
missing (*n*)	44	9	11		
Age groups % (*n*)				<0.001	0.041
≤ 29 yrs	10.7 (141)	13.0 (48)	18.2 (89)		
≥ 30 - ≤ 54yrs	30.4 (401)	28.0 (103)	30.7 (150)		
≥ 55 yrs	58.9 (777)	59.0 (217)	51.1 (250)		
missing (*n*)	45	12	7		
Devices % (*n*)				<0.001	<0.001
prostheses	14.8 (202)	13.2 (50)	7.5 (36)		
corsets	12.9 (176)	8.9 (34)	6.0 (29)		
stockings	20.0 (273)	14.2 (54)	6.8 (33)		
orthoses	15.0 (205)	12.6 (48)	15.6 (75)		
orthopaedic shoes	14.4 (196)	17.4 (66)	39.0 (188)		
shoe inlays	10.6 (144)	14.2 (54)	3.1 (15)		
prefab shoes	12.3 (168)	19.5 (74)	14.7 (71)		
various	-	-	7.3 (35)		
missing (*n*)	-	-	14		

Significantly more consumers were ≥ 55 years in the 2005-all group, compared to the 2002-group (p<0.001) and in the 2005-4 group compared to the 2002-group (p=0.041). The types of the devices provided differed significantly between the 2005-all group and 2002-group (p<0.001) and between the 2005-4 group and the 2002-group (p<0.001).

In table 1 the demographics and the devices provided have been summarised for the different groups. Significantly more consumers were ≥ 55 years in the 2005-all group, compared to the 2002-group (p<0.001) and in the 2005-4 group compared to the 2002-group (p=0.041). The types of the devices provided differed significantly between the 2005-all group and 2002-group (p<0.001) and between the 2005-4 group and the 2002-group (p<0.001).

Results of the comparison between the groups have been summarised in table 2. A mean overall rating of 8.1 (sd 0.9) was given to the P&O facilities by the 2005-all group (table 2). No significant differences were found in overall rating between the

different groups. No significant differences in mean overall rating were found between males and females in the 2005-all group, the 2005-4 group and the 2002-group. The mean rating of consumers ≥ 55 yrs was significantly higher than that of younger age groups, for the 2005-all group (p<0.001) and for the 2005-4 group (p=0.025). There was no significant difference in rating by consumers in the different age groups in 2002 (p=0.171). The mean rating differed significantly between consumers provided with different devices in the 2005-all group (p<0.001) in the 2005-4 group (p<0.001), and in 2002 (p=0.017). In ANOVA the interaction term "device x group" was significant (p=0.013) for the 2005-all group and the 2002-group. No other interaction terms were significant.

For the 2005-all group the mean time in years for using a device was 8.8 years (sd 11.8). A total of 93% of all consumers were satisfied with the delivery time, and 78% of all consumers were satisfied with their device, 3% were not satisfied and 19% did not know (yet) whether they were satisfied or not with their device. Of all these "not-knowers" (n=240) more than two-thirds gave a mean rating of ≥ 8, and 38% had been using their device less than a year.

Eight statements (50%) of the modified SERVQUAL fulfilled the criterion for a satisfactory quality (table 3). In the 2005-4 group the mean time in years for using a device was 8.5 years (sd 12.2). A total of 95% of them was satisfied with the delivery time, and 81% were satisfied with their device, 3% were not satisfied and 16% did not know (yet) whether they were satisfied or not with their device. In the 2005-4 group, seven statements (44%) of the modified SERVQUAL fulfilled the criterion for a satisfactory quality (table 3). In the 2002-group these numbers were 12 of the 14 statements (86%).

Table 2 Mean overall ratings, given to the P&O facilities by the consumers, divided into sex, age groups and devices provided.

	2005-all (n=1,364)	*2005-4 (n=380)*	*2002 (n=496)*	*Significance of the difference 2005-all and 2002*	*Significance of the difference 2005-4 and 2002*
Overall rating of ≥ 8	77% (*n*=977)	79% (*n*=277)	75% (*n*=231)		
Mean (sd)	8.1 (0.9)	8.1 (1.0)	8.0 (1.2)	0.180	0.178
Sex				0.845	0.545
male	8.1 (1.0)*	8.0 (0.9)*	8.0 (1.1)*		
female	8.1 (0.9)	8.2 (1.0)	8.0 (1.3)		
Age groups				0.635	0.696
≤29 yrs	7.8 (0.9)**	7.9 (1.0)**	7.9 (1.2)**		
≥30 - ≤54 yrs	8.0 (1.0)	8.0 (1.0)	7.9 (1.3)		
≥55 yrs	8.2 (0.9)	8.0 (0.9)	8.1 (1.1)		
Devices				0.013	0.282
prostheses	8.4 (1.0)***	8.6 (0.9)***	8.1 (1.0)***		
corsets	8.2 (0.9)	8.4 (1.0)	8.5 (1.1)		
stockings	8.1 (0.9)	8.1 (0.8)	8.3 (1.2)		
orthoses	8.0 (1.0)	8.5 (0.9)	8.1 (1.1)		
orthopaedic shoes	8.0 (1.0)	8.0 (1.0)	8.0 (1.1)		
shoe inlays	8.0 (0.7)	7.7 (0.6)	7.1 (1.1)		
prefab shoes	7.9 (0.9)	7.8 (1.0)	7.5 (1.6)		
various	-	-	8.1 (0.9)		

Within study groups

*No significant differences in overall rating were found between males and females.

**The mean rating of consumers ≥ 55 yrs was significantly higher than that of younger age groups, for the 2005-all group (p<0.001) and for the 2005-4 group (p=0.025). There was no significant difference in rating by consumers in the different age groups in 2002 (p=0.171).

***The mean rating differed significantly between consumers provided with different devices in the 2005-all group (p<0.001) in the 2005-4 group (p<0.001), and in 2002 (p=0.017).

Between study groups

Of all interaction terms, "sex x group", "age x group", and "device x group", only the "device x group" was significant for the 2005-all group and the 2002-group.

Table 3 The percentage of consumers who rated their "experience" of a certain statement equal to or higher than their rating of its "importance" is given for each of the 16 statements.

Statement	*2005-all*	*2005-4*	*2002*
	Exp ≥ Imp	Exp≥Imp	Exp ≥ Imp
Welcome	80	80	85*
Waiting time till next appointment	82	80	89*
Information on products of P&O facilities	66	66	78
Waiting times during visit	78	77	88*
Privacy in fitting rooms	75	72	86*
Conference with medical doctor	83	85*	92*
Consumer's wishes concerning cosmetics	86*	83	94*
Advice on use and maintenance of the device	88*	86*	93*
Attention and time for questions and remarks	90*	87*	95*
Delivery time for the device	90*	86*	NA
Contacts with health insurance	85*	85*	88*
Consumer centred	89*	87*	95*
Reachable by telephone	87*	84	88*
Reachable by means of public transport	78	76	NA
Parking space	86*	85*	86*
Well-appointed waiting room	76	75	76

Imp: Importance; Exp: Experience; NA: Not assessed in 2002.
Experience ≥ Importance: percentage of consumers who rated their "experience" equal to or higher than their "importance". * = Experience ≥ Importance by ≥ 85 % of the consumers

Discussion

The results of our study show that consumers gave the service provided at P&O facilities a mean rating of 8.1, and that they were generally satisfied both with the product and its delivery time. On the basis of these outcomes, it was expected that more statements on the SERVQUAL would have fulfilled the quality criterion.

As mentioned earlier, no other research regarding consumers' satisfaction with the services of P&O facilities has been published until now. Therefore, the outcomes of this study could only be compared with those of the study of 2002.[10] SERVQUAL outcomes were poorer in 2005 compared to those of 2002, while the criterion used for a satisfactory quality was similar to that of 2002. It may be that consumers are becoming more critical about the quality of service, that they are better informed through the internet, or that the quality of service has actually decreased since 2002.

Additionally, other factors not assessed (unknown confounders) may have influenced the differences in the results. Less than 75% of the consumers gave the statement about "Display of products at P&O facilities" a positive rating. This

result was against all expectations because, as a result of the outcomes in 2002, the management team took measures to improve these displays.

The overall high ratings of consumers in this study may be attributed to their dependency on their P&O facility.[10] However, discrepancies between moderate SERVQUAL outcomes and high consumer ratings have been published previously[19]. Several studies evaluating home- and community-based services, found that clients often gave high ratings on survey questions but when specific comments about services were asked, clients also reported serious deficiencies in worker performance, which were not reflected in the overall satisfaction rating.[19] It was hypothesised that longer relationship durations lead to changes in the nature of quality assessment because the level of experience and knowledge of the consumers grows, and the complexity of the relationship increases. Consumers have no choice but to accept the service, and also, different service experiences allow the consumers to focus more on the positive aspects of their experience.[19] Users of P&O facilities are often long-term care users and they have no other choice of P&O providers. Various methods for overcoming or minimising this effect mentioned above were recommended, very recently, by proposing modifications of the SERVQUAL to assess quality in a long-term care setting.[19]

In 2005 a mean overall rating of satisfaction of 8.1 was given by the consumers; this mean overall rating is slightly higher than in 2002. In 2005, consumers of ≥55 years gave a significantly higher rating than the other two age groups. Maybe younger consumers make higher demands on their devices, or are less easily pleased with the service of a P&O facility. The highest rating was given by consumers fitted with a prosthesis. To be able to function, these consumers are greatly dependent on a well-fitted prosthesis and hence, highly dependent on their P&O facility, which could be an explanation for a high rating.

It was also striking that 7% (n=85) of the consumers were not satisfied with the delivery time, while 30% of these dissatisfied consumers gave the facilities a rating of ≥ 8. The satisfaction with the delivered product shows the same pattern: 3% of the consumers were dissatisfied, while a third of them gave a rating of ≥ 8. In the 2005-all group 19% of the consumers answered that they did not yet know whether they were satisfied with the delivered product or not. From a management view, it is important to find out why this answer was given. Possibly, the consumers did not have an opinion yet, because they still had not had their device for a very long time, or perhaps they were unwilling or hesitant about giving their opinion, because of their being dependent on the P&O facility where they were treated.

At the start of the study the number of participants had been estimated to be 2,375 consumers. A total of 57% of the estimated number of questionnaires was filled out. However, it was not recorded how many consumers visited the P&O facilities during the survey period, and how many questionnaires were ultimately distributed to consumers at each facility. In only 45% of the questionnaires all statements were filled in. If this study is repeated, specific attention needs to be paid to the above-mentioned aspects. If, in future, consumers are asked to fill in the questionnaires on the spot, if they are assisted with the filling in, and if the questionnaires are supervised, the percentage of missing data would surely decrease. However, it may prove to be a disadvantage in cases where people do not feel free to give their opinion about the service provided.

From the point of view of the management of P&O facilities consumer satisfaction is economically important. It provides insight into topics that may improve the quality of the services provided.[10] However, consumer satisfaction is not only dependent on the service of a P&O facility, but also on the use and the functioning of the device and on the satisfaction with the cosmetics of the device. The SERVQUAL lacks assessment of these issues, so we would recommend the use of a more extensive questionnaire in future. Several questionnaires have been developed with a focus on consumers with a prosthesis.[6-8] The Prosthesis Evaluation Questionnaire (PEQ) was developed by Legro *et al.*[6], to be used for the evaluation of the effects of different types of prostheses or different methods of care. The Trinity Amputation and Prosthesis Experience Scales (TAPES) were developed by Gallagher and MacLachlan[8], to be used in the context of a multidimensional assessment of adjustment to a prosthetic limb. The Orthotics and Prosthetics Users' Survey (OPUS) was developed by Heinemann *et al.*[7], to evaluate the quality and effectiveness of the services provided by orthotics and prosthetics practices. Unfortunately, the results acquired from these questionnaires cannot easily be compared to our results, because different questions were asked, and different scales were used to weigh the answers to similar questions.

In future, it is important to continue to focus on consumer satisfaction by keeping in touch with the experiences and interests of consumers, in order to improve the quality of P&O services in daily practice. Additionally, more national and international collaboration with other research groups is required in order to develop a specific questionnaire to measure all aspects of prosthetic and orthotic care with the aim to improve the quality of the services.

Conclusion

The outcomes on the SERVQUAL are moderate. The overall consumer rating of the service provided by P&O facilities is high and people are satisfied with the product delivered and with the delivery time. To improve the services, development of a questionnaire to measure all aspects of prosthetic and orthotic care is recommended.

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Appendix

Questionnaire

1. The P&O facility staff give me the feeling that I am always welcome.
2. The prosthesist/orthotist/orthopaedic shoe technician is always willing to see me at short notice.
3. At the P&O facility there is a display in the hall or waiting room giving information on its products and services.
4. Waiting times during my visit to a P&O facility are short.
5. The fitting rooms and the training space offer good privacy.
6. The prosthesist/orthotist/orthopaedic shoe technician regularly confers with my medical doctor.
7. The prosthesist/orthotist/orthopaedic shoe technician respects my wishes concerning the appearance of the device.
8. The prosthesist/orthotist/orthopaedic shoe technician gives me clear advice on the use and maintenance of the device.
9. The P&O facility staff take my questions and remarks seriously.
10. The P&O facility delivers as agreed.
11. The P&O facility takes care of the contacts with my health insurance.
12. The P&O facility staff put my interests first.
13. The P&O facility is easy to reach by telephone.
14. The P&O facility is easy to reach by means of public transport.
15. The P&O facility offers enough parking space.
16. The P&O facility features a well-appointed waiting room.

Finally, we should like to obtain some extra information from you.

How long have you already used an orthopaedic device?	..... years
Are you satisfied with the delivered product?	Yes/no
Are you satisfied with our delivery time?	Yes/no/don't know
What is your sex?	Male/female
What is your age?	..... years old

Which rating do you give the service of the P&O facility on the whole, on a scale from 1 to 10?

Please circle the number you think appropriate.

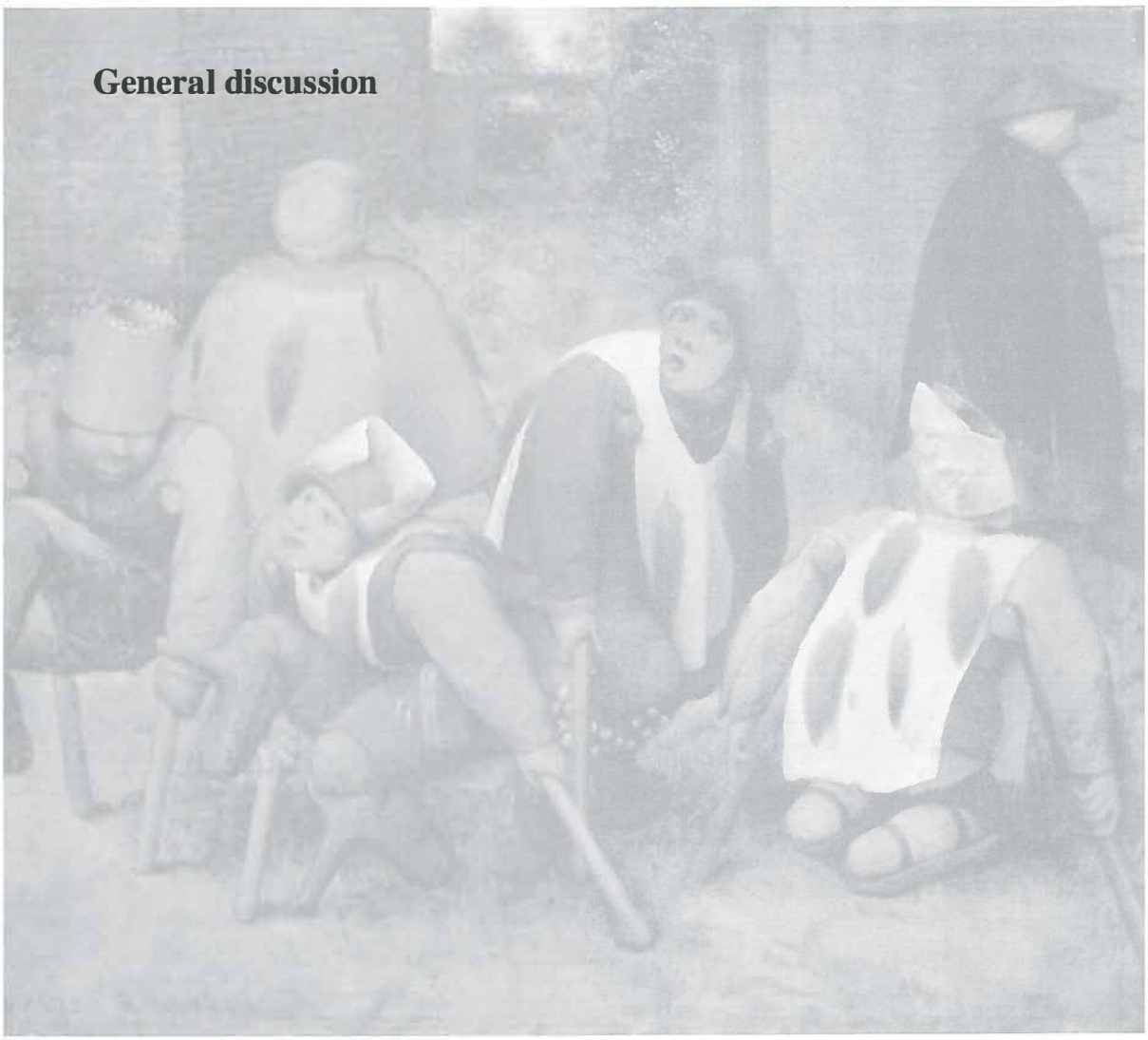
1 2 3 4 5 6 7 8 9 10

Should you have any suggestions or remarks that might improve our service, you may enter these here below.

Thank you very much for your cooperation.

Chapter 9

General discussion



Limb amputations have been with us throughout the ages. For patients a limb amputation has many consequences, both in functional, psycho-emotional and in social domains. Not only the amputation itself (and in the case of a traumatic amputation, the shock of such a sudden event), but also the impact of amputation-related pain on the person involved may be of great influence on someone's functioning. Furthermore, an amputation causes a possible dependence in the activities of daily living (ADL), a social dependence and, in the case of prosthesis supply, a dependence on prosthetics facilities. As mentioned in the introduction, worldwide research has been done on different aspects of amputation from the 1970's onwards. However, in general, each research project raises new questions. From the perspective of rehabilitation there are many burning questions which have to be answered and hence, investigated. From the patients' perspective it is important that the United Nations (UN) have made standard rules on the equalisation of opportunities for persons with disabilities in which the rights of disabled people have been laid down. Those rights include "the provision of rehabilitation services to persons with disabilities in order for them to reach and sustain their optimum level of independence and functioning" (rule 3) and "the development and supply of support services, including assistive devices for persons with disabilities, to assist them to increase their level of independence in their daily living and to exercise their rights" (rule 4).[1]
In this thesis a number of questions regarding different aspects and consequences of amputation have been investigated. Besides the chapters on the methodology used, this thesis contains a number of clinical studies on phantom pain as well as a study on consumer satisfaction. In this general discussion, we shall consider and discuss the implications of our research. This chapter concludes with recommendations for clinical practice and future research on the different topics.

In chapters 2 and 3, we have studied methodological aspects of an amputation, and phantom pain research. To clinicians it is obvious that the survival rates of patients with an amputation because of a vascular disease are moderate. In amputation research a lot of survival studies by means of historical cohort studies have been performed.[2-13] In those studies the total number of patients who were amputated was known and the number of deaths was recorded as a matter of course. In prospective studies, however, it is almost impossible to study a large, unbiased sample of amputees. As a result many studies have been carried out on a selected group of amputees only, such as patients who were referred for limb fitting or who

were rehabilitated in a rehabilitation centre and so, a considerable amount of bias occurred.[14-19]

In our prospective study concerning "survival of limb amputees in a prospective study; consequences for research" (chapter 2), it was previously agreed that all hospitals in the region should participate in the study (and in that way all potential candidates would be referred to the study). However, only about a third of the estimated number of all patients who were to undergo an amputation, was referred to our study. It appeared that hospitals did not participate and that surgeons who did participate did not refer all potential candidates. A limitation of our study was that the precise size of the bias could not be determined because the total number of amputees in the region was not known. The result of the study was that 73% of the participants and only 57% of the non-participants survived. Furthermore, substantial drop-out occurred during the study. It is important to organise a coherent, strong network of several persons who will be involved in the reference of patients (surgeons, ward doctors, physiotherapists employed in the different surgical departments, rehabilitation physicians) to be able to get as many patients referred as possible. Additionally, someone has to check all surgery schedules regularly, in order to be certain that all patients will be recruited. Other factors that might improve the recruitment are incentives for the people network, performing a pilot study to test recruitment procedure and providing the network with regular newsletters concerning study progress.[20-23] To minimise the number of drop-outs, several measures can be taken, viz.: take time to give clear information at first contact, make personal contact and keep in touch with the patients by newsletters, and render assistance with the follow-up questionnaires.

In chapter 3 insight has been given into the consequences of another methodological aspect of phantom pain. From the literature on the subject it is known that the prevalence rates of phantom pain range considerably: from 41% to 85%.[24-29] However, it is often unclear how, in the different studies, phantom pain is defined and how the frequencies of phantom pain are dichotomised. It is open to debate whether the finding that a patient who experiences phantom pain "a few times a year or a few times a month" is similar to the finding that a patient who experiences phantom pain "daily or always". In our study we have described the consequences of the application of different cut-off points. We found that, when other cut-off points were chosen, the prevalence rates we found differed, as did the risk factors. A limitation of this study was its cross-sectional design on the basis of questionnaires, so that bias in selection also occurred, viz. amputees who visited

prosthetics facilities. When researchers consider occurrence and impediment of phantom pain and report the choices they made in the analyses, it will be possible to compare and discuss the various prevalence rates and risk factors.

In chapter 4 the impact of an amputation and of phantom pain on the subjective well-being of amputees has been investigated in a qualitative study. Questions like: "What is the cause of bias in amputation research and what is the prevalence rate of phantom pain?" may offer a large amount of numerical data regarding the prevention of phantom pain, phantom sensations and stump pain, but they offer no information whatsoever about what phantom pain means to the amputee in his daily functioning. Furthermore, whether an amputee suffers phantom pain all the time or only a few times a month or a year, and whether he suffers much or little phantom pain, does not say anything about the impact that the phantom pain really has on him. And it is exactly these factors that are important from a rehabilitation perspective. In our qualitative study we have used a new socio-medical model (SPF theory - Social Production Function theory)[30], so it has been possible to gain a deeper understanding of social aspects which were not previously known. An advantage of this model is that in the case of pathology, e.g. in the case of an amputation, the amputee may influence his own well-being by dealing with his limitations and by using instrumental goals with their different factors in another way or intensity.[31,32] It seemed that all factors reinforced each other and that the greatest influence of factors on well-being occurred when more than one factor was involved. If there was a substitution of meaningful roles or activities, the sense of well-being increased. The impact of phantom pain as a single factor on social functioning was limited. No other studies on the social aspects of an amputation and its consequences have been performed. Till now subjective well-being and quality of life have been investigated mainly from the perspective of psychology.[33-35] Rehabilitation professionals must be aware of the different factors possibly influencing social functioning in amputees, especially when these factors occur simultaneously.

Up to now, few prospective studies on phantom pain have been performed, and if so, the long-term follow-up time seldom exceeded 1 year. Jensen's studies from 1983 and 1985 are still cited and his findings are still the standard.[25,36] It is important that many more prospective studies should be performed to gain insight into the aforementioned problems and consequences of an amputation in functional, psycho-emotional and social domains. Our prospective study on determinants of phantom pain (chapter 5) was a large study (n=85) with a follow-

up time to a maximum of 3½ years. A limitation of our study was that the only available Dutch questionnaires for assessing phantom pain had not been tested for reliability and validity. Disappointingly, determinants that can be changed were not found in limb amputees. To upper-limb amputees different treatments were available, such as intensive use of a myoelectric prosthesis[37], a daily discrimination training of electrical stimuli to a stump[38], and mirror treatment[39,40] which all claim to have an influence on phantom limb pain.

The advantages of performing a knee disarticulation (KD) (chapter 6) instead of a transtibial (TTA) or a transfemoral amputation (TFA) have been described in literature. The claim that this operation technique clinically offers a patient a better stability of walking (and in that way, a better mobility) as well as resulting in lower mortality rates, cannot really be supported by our study. However, a comparison of the outcomes of our historical cohort study on survival, wound healing and ambulation after a KD with previous studies is rather difficult because the mean age of the amputees in our study was 79 years, which was considerably older than the amputees in other studies. Furthermore, different follow-up periods investigating the mortality rates were used in the various studies, and the rates of prosthesis provision and ambulation were calculated in different ways. The advantages of a KD can easily be confounded by indication, especially in the elderly. To gain evidence for the advantages of a KD, randomised clinical trials (RCT) are needed.

In our study about claimed walking distance (chapter 7) (the ability to walk a certain distance), it appeared that the chance of being able to walk 500 m or more decreased with an increase in age, a more proximal level of amputation, a vascular reason for amputation and also in cases where phantom pain and/or stump pain was present. In general, the ability to walk and the ability to cover a reasonable distance are of major importance in retaining ADL independence and social mobility. It is supposed that a walking distance of at least 500 m is needed to function independently. When a person is able to walk such a distance, he is ADL independent indoors as well as outdoors (possibility to walk from the parked car to a shop, to visit shops in the neighbourhood, recreational possibilities). The ability to walk also depends on the possibility of fitting a prosthesis.[41-43] In order to have the ability to walk well an appropriate prosthesis fitting has to be prescribed, and with a walking distance of 500 m or more other requirements are demanded of a prosthesis. It is known that walking distance and prosthesis prescription depend on the age, the profession and on the amputee suffering comorbidity, on the reason for

and the level of amputation, on the stump condition, and on stump pain and phantom pain. The influence of all those factors on walking distance has been analysed univariately. However, it is precisely the cumulative effects of the variables on walking distance that can give more information and can be used to predict the chance to walk 500 m or more. And the chance of an amputee regaining the ability to walk will influence the prescription of a prosthesis. We have done a cross-sectional study by means of questionnaires, but it is important to measure the actual walking distance. In future studies it will be important to follow amputees prospectively to verify the prediction of the walking distance in the long run.

In chapter 8 consumer satisfaction with the services of prosthetics and orthotics (P&O) facilities has been compared with a previous study, also carried out by our clinic.[44] The outcomes of 2005 showed a few differences with 2002, but the overall rating in both studies was high. As a result of the outcomes of the 2002 study certain improvements were made. However, against all expectations, in 2005 75% of the consumers gave one of these improvements a low rating. It may be that consumers were becoming more critical about the quality of the services in 2005. Hence, considering the perspective of the present time, the social context, and considering the fact that consumers are better informed by means of the internet, it is important to study consumer satisfaction extensively and regularly, again and again, in order to improve the quality of P&O services in daily practice. Besides the quality of P&O facilities, all aspects of P&O care, such as functional status with a prosthesis or orthosis, consumer satisfaction with a prosthesis or orthosis and the quality of life in the field of prosthetics and orthotics, should be measured.[45-47] For this purpose, however, national and international collaboration is required to develop specific measuring instruments or questionnaires. In this day and age it is not feasible any more that everyone should be using his/her own questionnaires and measuring methods. Maybe the International Society for Prosthetics and Orthotics (ISPO) can take the initiative to develop an international useable instrument about which international consensus will exist and which can be used worldwide.

Recommendations for future research

Insight into the rehabilitation wants and wishes of the elderly, vascular amputee is needed. A lot of time, money and research is spent on new advanced prostheses for the benefit of younger amputees; prostheses with which the most splendid (sporting) successes can be achieved by a small select group of patients. Most amputations, however, are performed on elderly patients suffering from extensive vascular problems. In general, these patients have a limited life expectancy and many are not suitable candidates for prosthesis training. Rehabilitation after an amputation, however, does not only include prosthesis training but also transfer training, wheelchair training and attention to amputees' quality of life. It is recommended that, in future, treatment plans and treatments for the elderly with an amputation due to a vascular disease should be developed, and that more research should be done on elderly amputees, in the fields of prosthetic rehabilitation, functional outcome after amputation and quality of life.

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Summary

Limb amputation and prosthetic replacement have been known for centuries, both through the spoken and the written word. The large number of great wars waged in the 19th and 20th centuries made it possible for surgeons to focus their attention on improving amputation techniques. And after the Second World War, large research projects on amputation and prostheseology were started up in various countries. Furthermore, research was done on other aspects of amputation as well, like risk factors of phantom pain and phantom sensations, prevention of phantom pain, stump problems/skin problems after amputation, survival/mortality after amputation functional outcome after amputation, quality of life/subjective well-being of amputees and sexuality after amputation. Actually, from the moment the medical world started to spend time, money and interest on research, amputees have been taken more seriously and more attention has been paid to amputees' questions. Various studies on different aspects of amputation have already been performed, but from these studies other new questions arise. This thesis has investigated and answered a number of these questions.

After a general introduction (chapter 1) the results of a prospective, multicentre cohort study on the extent and type of selection in a limb amputees' study population were presented in chapter 2. From historical cohort studies it is known that the survival rate of patients with a vascular amputation rates from 36% to 66% in the first 2 years after amputation. In those studies the total number of patients who were amputated was known and the number of deaths was recorded as a matter of course. In prospective studies it is almost impossible to study a large, unbiased sample of amputees. Many studies were carried out on a selected group of amputees only, such as patients who were referred for limb fitting or who were rehabilitated in a rehabilitation centre and so, it is obvious that a considerable amount of bias occurred, but the extent of bias is unknown. In our study we analysed the survival rate of 214 patients scheduled for a limb amputation and referred to our study on phantom pain and phantom sensations. Of these patients referred, 134 (63%) participated in the prospective study by questionnaires (participants); the others (non-participants) were followed over time through records. More non-participants than participants were amputated because of a peripheral vascular disease (PVD) (83% (n=66) and 67% (n=90), respectively); the other reasons for amputation were cancer and trauma. Sixty percent of all patients referred survived in the 4-year period after amputation, but more participants (68%) survived, as compared to non-participants (44%). The mean survival time of

participants was 36.1 months, while the mean survival time of non-participants was 27.1, but both participants and non-participants with an amputation due to PVD had a shorter life span than those with an amputation due to cancer or a trauma. So it would seem that participants were in better general health than non-participants. Furthermore, it was previously agreed that all hospitals in the region were to participate in the study. However, only about a third of the estimated number of all patients who were to undergo an amputation, was referred to our study. The precise size of the bias could not be determined. Thus our study sample was biased by selection and death.

One of the phenomena occurring after an amputation is phantom (limb) pain. In medical literature prevalence and incidence rates of phantom pain for all limb amputees range considerably, from 41% to 85%. Should a clinician tell the patient in clear terms what phantom pain is, more realistic figures would probably emerge. Furthermore, one should ask oneself whether amputees suffering from phantom pain "a few times a year or a few times a month", may be compared to amputees suffering from phantom pain "daily or always". In literature there is usually no indication whether these amputees were all thrown together or whether a distinction was made between the different groups. Chapter 3 offered an analysis of how decisions to dichotomize the frequency and impediment of phantom pain into absent and present influenced the outcome of studies. Our study showed that, when different cut-off points for the frequency of phantom pain were applied, the prevalence of phantom pain ranged considerably, from 9% to 72%. Furthermore, the significance of the relationship between different risk factors and phantom pain also changed. The choice of cut-off points influenced the outcome of phantom pain studies considerably. The study provided some insight into the differences in prevalence and risk factors found in literature.

Chapters 2 and 3 may have offered a large amount of numerical data regarding the prevalence rate of phantom pain, phantom sensations and stump pain, but no information whatsoever about what phantom pain means to the amputee. In chapter 4 we examined the impact of an amputation and of phantom pain on the subjective well-being of amputees in a qualitative study. To investigate the impact on the patient himself, 16 lower limb amputees were interviewed by means of a semi-structured interview and two Visual Analogue Scales. Questions were asked concerning the factors influencing the patients' subjective well-being prior to, at

the time of and after an amputation. These factors were the patients' medical history, their phantom sensations and phantom pain, their daily activities, the social support they received, and the influence of an amputation and phantom pain on their long-term behaviour and subjective well-being. For the interpretation of the results of this qualitative study, a new socio-medical model joining two models, 'The Disablement Process Model', and the 'Social Production Function theory', was used. For the majority of the patients the direct influence of phantom pain on their subjective well-being appeared to be small, but unbearable phantom pain was found to have quite a large influence. All factors were found to have a certain influence on the individual's subjective well-being. However, the factors seemed to reinforce each other. Therefore, the greatest influence of factors on subjective well-being occurred when more than one factor was involved. The influence on their well-being was found to be less for patients who were physically independent, had a job, had a partner and friends, and had prospects, as compared to patients who had no substitution of meaningful roles or activities.

The objective of the study described in chapter 5 was to analyse the prevalence of phantom limb pain (PLP) over time and the determinants of PLP in a 3½-year multicentre longitudinal study on phantom sensations, phantom pain and stump pain. Until now, few prospective studies have been performed on phantom pain, and the studies that have been done had relatively small population samples and the long-term follow-up seldom exceeded 1 year. In our study patients scheduled for an amputation filled in the 'Groningen Questionnaire Problems after Leg Amputation (GQPLA) or, in case of an upper-limb amputation, the 'Groningen Questionnaire Problems after Arm Amputation (GQPAA)' before amputation, as well as postal questionnaires 6 months, 1½ years, and 2½ years to a maximum of 3½ years after amputation. Preoperative assessment included patients' characteristics (date of birth, sex) and date, side and level of, and reason for amputation. The follow-up questionnaires assessed the frequencies of the experienced PLP, prosthetic use and walking distance. Pre- and postoperative questionnaires were available, filled in by 85 amputees (33 females and 52 males). In general, more women than men experienced PLP and the percentage of amputees with PLP was the lowest at 6 months and 1½ years after amputation. One and a half years and 2½ years after amputation the highest percentages of the lower-limb amputees used their prosthesis ≥ 4h/day (66% and 68%, respectively), after that time this percentage decreased to 56%. However, of the upper-limb

amputees only 22% used their prosthesis ≥ 4h/day at 1½ years, before and after that time upper-limb amputees used their prosthesis < 4 h/day. It appeared that the chance of experiencing phantom limb pain (PLP) was less in men as compared to women, less in lower-limb amputees as compared to upper-limb amputees, and the chance of experiencing PLP decreased over time. Other risk factors, viz. age, reason for or level of amputation, prosthetic use and, in the case of lower-limb amputees, walking distance, were not associated with the chance of experiencing PLP.

A special type of amputation is the knee disarticulation. It is claimed to offer a considerable walking stability, hence a better mobility, with a limited mortality. This clinical claim was investigated in a historical cohort study, performed in the hospital of Drachten, using medical records and nursing home records of 80 amputees. In chapter 6 the results of this study were reported and discussed. The mean age of amputees was 76.9 (± 9.6) years and the median follow-up time was 9.9 years. The main reason for amputation was gangrene, but most amputees had a peripheral arterial disease as a concomitant disease; other concomitant diseases were a cardiovascular disease, a cerebrovascular disease and diabetes mellitus. Patients with two or more concomitant diseases more frequently had a delayed wound healing than patients with one or no concomitant disease. Survival of the patients after 1, 6 and 12 months was 87%, 65% and 52%, respectively. Of the 61 discharged knee-disarticulation amputees, 36 (59%) were provided with a prosthesis and 58% of those became household walkers. Clinically, amputation should be regarded as a reconstructive procedure that is designed to restore function and to allow the patient to return to an independent lifestyle. Ambulation after amputation, with or without the use of aids, represents a major achievement. The claim that this operation technique clinically offers a patient a better stability of walking (and in that way, a better mobility) as well as resulting in lower mortality rates, cannot really be supported by our study.

For lower-limb amputees, the ability to walk and the ability to cover a reasonable distance are of major importance in retaining independence and social mobility. Especially elderly amputees are often limited in their walking ability because they suffer not only from diabetes mellitus or a vascular disease but also from osteoarthritis. In chapter 7 different factors influencing the ability to walk a distance of 500 metres or more were investigated and analysed. A total of 437

patients returned the 'Groningen Questionnaire Problems after Leg Amputation', in which walking distance was assessed, and the RAND-36. It appeared that the chance of walking a distance of 500 m or more reduced when a transfemoral amputation was performed. When phantom pain or stump pain were present, the chance reduced even more. And if the amputation was performed because of a vascular disease or because of vascular problems due to diabetes, the chance reduced again. Independently of these factors, the chance of walking 500 m or more reduces with an increase in age.

The objective in chapter 8 was to analyse consumer satisfaction regarding the services provided by 15 prosthetics and orthotics (P&O) facilities in the Netherlands. In the course of time, many amputees are fitted with one or more prostheses. This fitting is done in P&O facilities that offer other services, such as orthopaedic shoes, an orthosis, shoe inlays, prefab shoes, a corset or stockings. Nowadays, consumers of P&O facilities do not only require the very best device, their satisfaction with the service of the facilities is very important, too. So the facilities have to keep asking themselves the question whether their service is still up-to-date, and whether improvements should be made. Up to now consumer satisfaction with the services provided in a facility has seldom been studied. Consumers (n=1,364) of these P&O facilities who were fitted with a prosthesis or another device were asked to rate the overall services provided and whether they were satisfied with the device provided and its delivery time. Additionally, they filled in a modified SERVQUAL questionnaire. Consumers gave the service provided by the P&O facilities a mean overall rating of 8.1. The highest ratings were given by consumers fitted with a prosthesis (mean overall rating of services: 8.4). In total, 78% of the consumers were satisfied with the device provided and 93% with the delivery time. The results of our study showed that, on the SERVQUAL, 50% of the statements fulfilled the criteria for a satisfactory quality of the services. The overall consumer rating of the service provided by P&O facilities was high. In future, it is important to focus on consumer satisfaction by keeping in touch with the experiences and interests of consumers, in order to improve the quality of P&O services in daily practice. Additionally, specific questionnaires need to be developed to measure all aspects of prosthetic and orthotic care, with the aim to improve the services.

In the general discussion (chapter 9) the clinical implications of our research were discussed. As said, various studies on different aspects of amputation have already been performed, and from these studies other new questions have arisen. Our studies, as described in the different chapters, have also raised new questions which need to be answered. The chapter concluded with recommendations for clinical practice and future research. Most amputations are performed on elderly patients suffering from extensive vascular problems. Insight into the rehabilitation wants and wishes of the elderly, vascular amputee is needed. In future, treatment plans and treatments for the elderly with an amputation due to a vascular disease should be developed, and more research should be done on elderly amputees, in the fields of prosthetic rehabilitation, functional outcome after amputation and quality of life.

Samenvatting

Het amputeren van een arm of been en de vervanging van het lichaamsdeel door een prothese zijn al eeuwen in woord en geschrift bekend. Door het grote aantal oorlogen in de 19de en 20ste eeuw en de bijbehorende slachtoffers werden chirurgen gedwongen aandacht te schenken aan verschillende amputatietechnieken en deze te verbeteren. Na de Tweede Wereldoorlog werden in diverse landen grote onderzoeksprojecten naar amputatie en prothesiologie gestart. Ook werd onderzoek gedaan naar risicofactoren voor fantoompijn en fantoomsensaties, preventie van fantoompijn, stomppijn/huidproblemen na amputatie, overleving/mortaliteit na amputatie, functionele uitkomsten na amputatie, kwaliteit van leven/subjectief welbevinden van mensen met een amputatie en seksualiteit na amputatie. Vanaf het moment dat de medische wereld tijd, geld en aandacht aan onderzoek besteedde, werden mensen met een amputatie serieuzer genomen en kwam er meer belangstelling voor vragen van mensen met een amputatie. Diverse studies over verschillende aspecten van amputatie zijn al verricht, maar deze studies roepen ook weer nieuwe vragen op. Dit proefschrift heeft een aantal van deze vragen onderzocht en beantwoord.

Na een algemene inleiding (hoofdstuk 1) zijn in hoofdstuk 2 de resultaten van een prospectieve, multicentre cohort studie naar de omvang en het type van selectie in een populatie mensen met een amputatie gepresenteerd. Uit historische cohort studies is bekend dat de overleving van patiënten met een amputatie ten gevolge van vaatlijden in de eerste 2 jaar na amputatie tussen de 36% en 66% ligt. In die studies was het totale aantal patiënten dat geamputeerd werd bekend, evenals het aantal overleden patiënten. In prospectieve studies is het bijna onmogelijk om een uitgebreide, niet vertekende steekproef van mensen met een amputatie te bestuderen. Veel van de prospectieve studies zijn alleen uitgevoerd op een selecte groep mensen met een amputatie, zoals patiënten die verwezen werden voor een prothesevoorziening of die werden gerevalideerd in een revalidatiecentrum. Het was duidelijk dat een selectie was opgetreden, maar de omvang daarvan was onbekend. In onze studie hebben wij de overlevingscijfers van 214 patiënten die gepland stonden voor een amputatie en die verwezen werden naar onze studie naar fantoompijn en fantoomsensaties geanalyseerd. Van deze verwezen patiënten namen 134 (63%) deel aan de prospectieve studie door middel van vragenlijsten (deelnemers); de anderen (niet- deelnemers) werden gevolgd in de tijd door bestudering van medische dossiers. Meer niet-deelnemers dan deelnemers werden geamputeerd vanwege een perifeer vaatlijden (respectievelijk 83% (n=66) en 67%

(*n*=90)); de andere redenen voor amputatie waren kanker of een ongeluk. Zestig procent van alle verwezen patiënten overleefden de eerste vier jaar na amputatie, maar meer deelnemers (68%) dan niet-deelnemers (44%) overleefden. De gemiddelde overleving van de deelnemers was 36,1 maanden, terwijl de gemiddelde overlevingstijd van de niet-deelnemers 27,1 maanden was. Zowel de deelnemers als de niet-deelnemers met een amputatie vanwege een perifeer vaatlijden leefden korter dan degenen met een amputatie vanwege kanker of een ongeluk. Van tevoren was afgesproken dat alle ziekenhuizen in de regio zouden deelnemen aan de studie. Echter, alleen een derde van het geschatte aantal patiënten dat een amputatie zou ondergaan werd verwezen naar onze studie. De precieze omvang van het totale aantal amputaties kon niet vast gesteld worden. Dus onze studiesteekproef werd vertekend door selectie en mortaliteit.

Een van de fenomenen die optreden na een amputatie is fantoompijn. In de medische literatuur variëren prevalentie- en incidentiecijfers voor fantoompijn tussen de 41% en 85%. Men moet zich echter afvragen of mensen met een amputatie die "een paar keer per jaar of een paar keer per maand" fantoompijn hebben vergeleken mogen worden met hen die "dagelijks of altijd" fantoompijn hebben. In de regel wordt in de literatuur niet aangegeven of er een onderscheid wordt gemaakt tussen de verschillende groepen. Hoofdstuk 3 gaf een analyse van de manier waarop beslissingen om een tweedeling te maken in afwezig of aanwezig, wat betreft de frequentie van en belemmeringen veroorzaakt door fantoompijn, de uitkomsten van studies beïnvloedde. Onze studie toonde aan dat, wanneer verschillende afkappunten voor de frequentie van fantoompijn werden toegepast, de prevalentie van fantoompijn aanzienlijk varieerde: tussen de 9% en 72%. Tevens veranderde de significantie van de relatie tussen de verschillende risicofactoren en fantoompijn. De keuze van afkappunten beïnvloedde de uitkomst van fantoompijnstudies aanzienlijk. De studie gaf inzicht in de mogelijke redenen voor verschillen in prevalentie en risicofactoren zoals gevonden in de literatuur.

Hoofdstukken 2 en 3 gaven getalsmatig de prevalentie van fantoompijn, fantoompijn en stomppijn weer, maar ze bevatten geen informatie over wat fantoompijn werkelijk betekent voor iemand met een amputatie. In de kwalitatieve studie beschreven in hoofdstuk 4 onderzochten wij de invloed van een amputatie en van fantoompijn op het subjectieve welbevinden van mensen met een amputatie. Hiervoor werden 16 patiënten met een beenamputatie geïnterviewd door middel

van een semigestructureerd interview en door het afnemen van twee Visueel Analoge Schalen. Gevraagd werd naar de factoren die het subjectieve welbevinden van een patiënt voor, tijdens en na de amputatie beïnvloedden. Deze factoren waren de medische voorgeschiedenis van de patiënt, zijn ervaren fantoomsensaties en fantoompijn, zijn dagelijkse activiteiten, de sociale ondersteuning die hij ontving en de invloed van de amputatie en van fantoompijn op zijn gedrag op de langere termijn en op zijn subjectieve welbevinden. Om de resultaten van deze kwalitatieve studie te kunnen interpreteren werd een nieuw sociomedisch model, verkregen door samenvoeging van 'The Disablement Process Model', en 'The Social Production Function theory', gebruikt. De directe invloed van fantoompijn op het subjectieve welbevinden leek voor het merendeel van de patiënten klein, maar ondraaglijke fantoompijn had een vrij grote invloed. Er kwam naar voren dat alle factoren enige invloed hadden op het subjectieve welbevinden. De grootste invloed van factoren op het subjectieve welbevinden trad op als er meer dan een factor in het spel was. De invloed op het welbevinden was minder groot bij patiënten die onafhankelijk waren, een baan hadden, een partner en vrienden hadden en vooruitzichten hadden, dan bij patiënten die geen vervanging van betekenisvolle taken of activiteiten hadden gevonden.

Het doel van de studie, beschreven in hoofdstuk 5, was het analyseren van de prevalentie van fantoompijn in verloop van de tijd en van determinanten van fantoompijn in een 3½ jaar durende multicentre cohort studie. Tot nu toe zijn weinig prospectieve studies naar fantoompijn gedaan en de studies die gedaan zijn, hadden een betrekkelijk kleine steekproef en de langetermijnfollow-up overschreed zelden 1 jaar. In onze studie vulden patiënten, gepland voor een amputatie, voor de operatie (preoperatief), 6 maanden, 1½, 2½ tot maximaal 3½ jaar na de operatie (postoperatief) de 'Groningen Vragenlijst voor Problemen na een Beenamputatie' in of, in geval van een armamputatie, de 'Groningen Vragenlijst voor Problemen na een Armamputatie'. Het preoperatieve onderzoek vroeg naar kenmerken van de patiënt (geboortedatum en geslacht), de hoogte en zijde van amputatie en de reden voor amputatie. De postoperatieve vragenlijsten vroegen naar de frequenties van de ervaren fantoompijn, het prothesegebruik en de loopafstand. Er waren pre- en postoperatieve vragenlijsten beschikbaar, ingevuld door 85 patiënten (33 vrouwen en 52 mannen). In het algemeen ervoeren meer vrouwen dan mannen fantoompijn en het percentage patiënten met fantoompijn was het laagst op 6 maanden en 1½ jaar na amputatie. Anderhalf en 2½ jaar na amputatie gebruikten het hoogste aantal

patiënten met een beenamputatie hun prothese ≥ 4^{u}/dag (respectievelijk 66% en 68%), na die tijd daalde dit aantal naar 56%. Echter, slechts 22% van de mensen met een armamputatie gebruikten na 1½ jaar hun prothese ≥ 4^{u}/dag, voor en na die tijd gebruikten de patiënten hun prothese < 4^{u}/dag. Het bleek dat mannen minder kans hadden fantoompijn te ervaren dan vrouwen, mensen met een beenamputatie minder kans dan patiënten met een armamputatie, en dat de kans om fantoompijn te ervaren in de loop van de tijd afnam. De kans op fantoompijn en andere potentiële risicofactoren, namelijk leeftijd, reden en hoogte van amputatie, prothesegebruik en, in geval van een beenamputatie, loopafstand konden niet met elkaar in verband worden gebracht.

Een speciaal type beenamputatie is de knie-exarticulatie. Er wordt van beweerd dat deze amputatie een aanzienlijke loopstabiliteit geeft (en daarom een betere mobiliteit) en een beperkte mortaliteit kent. Deze klinische bewering werd onderzocht in een historische cohort studie, uitgevoerd in het ziekenhuis van Drachten, waarbij gebruikgemaakt werd van medische dossiers van 80 patiënten met een amputatie. In hoofdstuk 6 zijn de resultaten van deze studie beschreven en bediscussieerd. De gemiddelde leeftijd van de patiënten was 76,9 (± 9,6) jaar en de mediaan van de vervolgtijd was 9,9 jaar. De voornaamste reden van amputatie was gangreen, maar de meeste patiënten hadden een perifeer vaatlijden als bijkomende aandoening; andere bijkomende aandoeningen waren hartvaatziekten, hersenvaatziekten en suikerziekte. Patiënten met twee of meer bijkomende ziekten hadden vaker een tragere wondgenezing dan patiënten met een of geen bijkomende ziekte. Overleving van patiënten na 1, 6 en 12 maanden was respectievelijk 87%, 65% en 52%. Van de 61 ontslagen patiënten kregen er 36 (59%) een prothese. Strikt objectief gezien moet een amputatie gezien worden als een reconstruerende procedure met als doel de functie te herstellen en de patiënt terug te laten keren naar een onafhankelijke manier van leven. Met of zonder hulpmiddelen rondlopen na een amputatie betekent een grote prestatie. De claim dat de knie-exarticulatie de patiënt een betere loopstabiliteit (en op die manier een betere mobiliteit) geeft, alsook dat dit soort amputatie een lagere mortaliteit heeft, kan niet door onze studie ondersteund worden.

Voor mensen met een beenamputatie is het vermogen om te lopen, en dan ook nog een redelijke afstand te overbruggen, van groot belang om hun onafhankelijkheid en sociale mobiliteit te behouden. Vooral oudere patiënten zijn vaak beperkt in hun

loopmogelijkheden omdat ze niet alleen lijden aan suikerziekte of aan hart- en vaatziekten maar ook aan gewrichtsslijtage. In hoofdstuk 7 zijn verschillende factoren die het vermogen om 500 m of meer te lopen onderzocht en geanalyseerd. In totaal 437 patiënten stuurden de 'Groningen Vragenlijst Problemen na Beenamputatie', waarin loopafstand werd onderzocht, terug. Het bleek dat de kans om 500 m of meer te kunnen lopen kleiner werd wanneer een bovenbeen was geamputeerd. Als er sprake van fantoompijn of stomppijn was, verminderde die kans nog meer. Als de amputatie verricht was vanwege een vaatlijden of door suikerziekte veroorzaakte vaatproblemen, dan werd die kans nog kleiner. Onafhankelijk van deze factoren gaf een stijging in leeftijd een vermindering van de kans om 500 m of meer te kunnen lopen.

Het doel van het onderzoek beschreven in hoofdstuk 8 was om de klanttevredenheid betreffende de service van 15 orthopedische instrumentmakerijen (OIM) in Nederland te onderzoeken. In de loop van de tijd krijgen veel mensen met een amputatie één of meer protheses. Deze voorziening wordt gemaakt in instrumentmakerijen die ook andere voorzieningen aanmeten, zoals orthopedisch schoeisel, een orthose (een uitwendig gedragen hulpmiddel ter correctie of ondersteuning), inlegzooltjes voor schoenen, prefab schoeisel, een korset of kousen. Tegenwoordig eisen consumenten niet alleen de beste voorziening van orthopedische instrumentmakerijen, maar hun tevredenheid met de service van de instrumentmakerijen is ook zeer belangrijk. De instrumentmakerijen moeten zich dus steeds blijven afvragen of hun service nog up-to-date is en of er verbeteringen aangebracht moeten worden. Tot nu toe is de klanttevredenheid met de diensten aangeboden door een instrumentmakerij nog maar zelden onderzocht. Consumenten (n=1364) van de 15 orthopedisch instrumentmakerijen die een prothese of een van de andere voorzieningen kregen aangemeten, werd gevraagd een cijfer te geven voor de verleende service en of ze tevreden waren met de verstrekte voorziening en met de leveringstijd. Bovendien vulden ze een gemodificeerde SERVQUAL vragenlijst in. Consumenten gaven de verleende service een gemiddeld totaal cijfer van 8,1. De hoogste cijfers werden gegeven door consumenten die een prothesevoorziening kregen (gemiddeld totaalcijfer 8,4). Achtenzeventig procent van de consumenten was tevreden met de verstrekte voorziening en 93% met de leveringstijd. De resultaten van onze studie toonden aan dat 50% van de SERVQUAL stellingen beantwoordden aan de maatstaven voor een voldoende kwaliteit van instrumentmakerijen. Het totaalcijfer van de

consumenten voor de service, zoals verstrekt door de orthopedische instrumentmakerijen, was hoog. Ten einde de kwaliteit van de instrumentmakerijen in de dagelijkse praktijk te blijven verbeteren, is het belangrijk om op de hoogte te blijven van de ervaringen en belangen van de consumenten. Bovendien moeten specifieke vragenlijsten ontwikkeld worden om alle aspecten van prothese- en orthesezorg te meten, zodat de service nog meer verbeterd kan worden.

In de algemene discussie (hoofdstuk 9) zijn de klinische gevolgen van de onderzoeken besproken. Zoals eerder gezegd, zijn er al diverse studies over verschillende aspecten van amputatie verricht en vanuit deze studies zijn ook weer nieuwe vragen gerezen. Het hoofdstuk eindigde met aanbevelingen voor de klinische praktijk en voor toekomstig onderzoek. De meeste amputaties worden verricht op oudere patiënten met uitgebreid vaatlijden. Inzicht in de revalidatiewensen en -behoeften van deze ouderen is nodig. In de toekomst zullen behandelplannen en behandelingen voor de oudere met een amputatie ontwikkeld moeten worden, en er zal meer onderzoek gedaan moeten worden naar de oudere met een amputatie op het terrein van protheserevalidatie, de functionele uitkomst na amputatie en naar de kwaliteit van leven.

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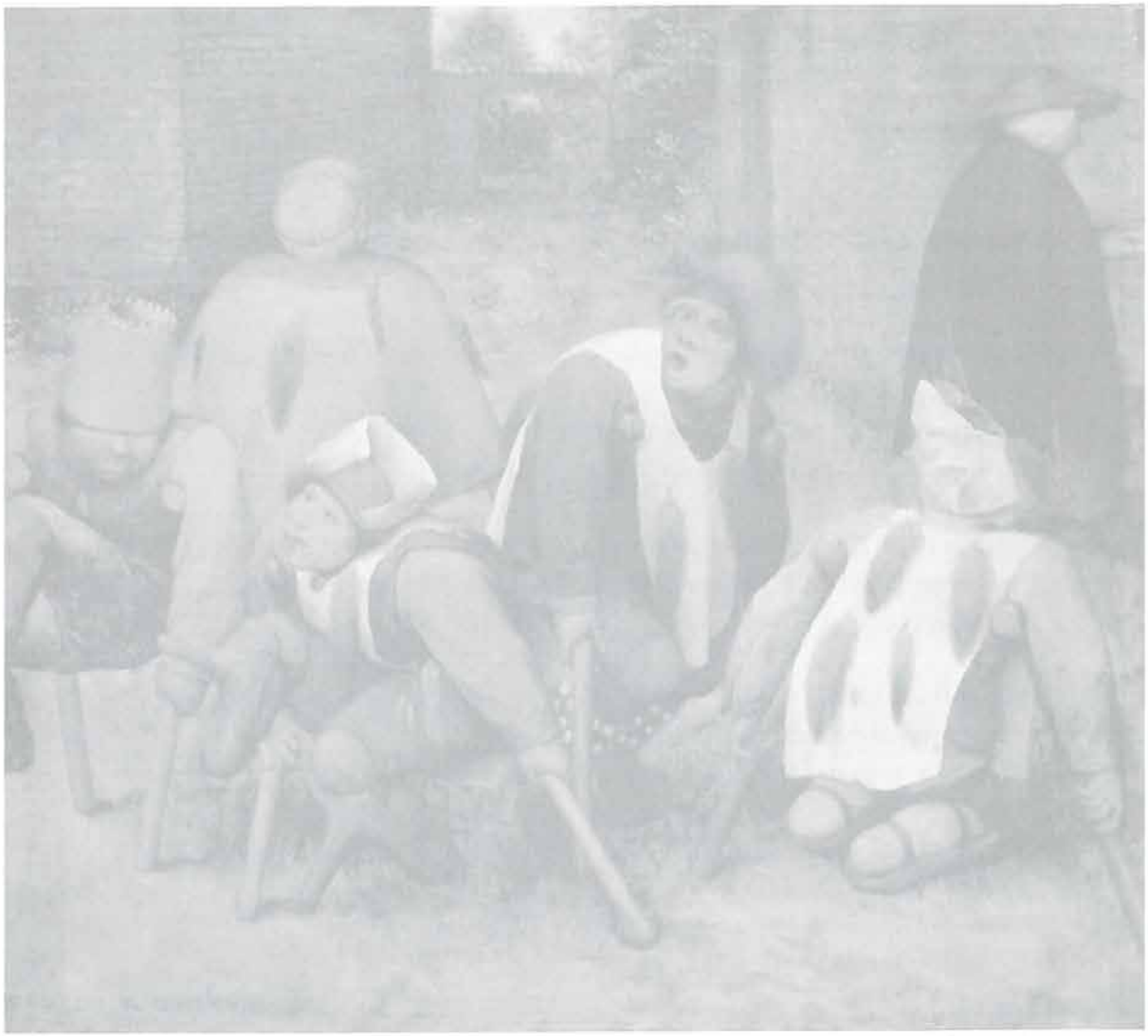

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